Calendar No. 586

109TH CONGRESS, *2d Session* | SENATE | REPORT 109–324

DIETARY SUPPLEMENT AND NONPRESCRIPTION DRUG CONSUMER PROTECTION ACT

SEPTEMBER 5, 2006.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 3546]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 3546) to amend the Federal Food, Drug, and Cosmetic Act with respect to serious adverse event reporting for dietary supplements and nonprescription drugs, and for other purposes, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill, as amended, do pass.

CONTENTS

I. PURPOSE AND SUMMARY OF THE BILL

The purpose of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, S. 3546, is to establish a mandatory reporting system of serious adverse events for non-prescription (also known as "over-the-counter") drugs and dietary supplements sold and consumed in the United States. The bill amends Chapter VII of the Federal Food, Drug, and Cosmetic Act (FFDCA) to set

up two, new, parallel, mandatory reporting systems, one for non-prescription drugs, and the other for dietary supplements.

II. Background and Need for Legislation

Millions of Americans daily rely on over-the-counter drugs and dietary supplements. The vast majority of these products are safe, but the public could benefit from a system to ensure that government officials are made aware of any serious problems that arise.

Although the Food and Drug Administration has a voluntary system to receive reports about adverse events with dietary supplements, and a mandatory system that covers some non-prescription drugs, there is no requirement for mandatory reporting for all of these products as there is with other FDA-regulated products such as prescription drugs and medical devices. This bipartisan bill would require manufacturers and distributors of these products to report all serious adverse events to the government.

The Dietary Supplement Health and Education Act (DSHEA) of 1994 [Public Law 103–417] ensures that a broad array of dietary supplements, and information about the benefits of those products, is available to American consumers. With this new bill, DSHEA will continue to protect consumer choice and access to dietary supplements that are safe and properly labeled. At the same time, consumers will benefit from a new system to make certain problems that arise are identified quickly so that they can be addressed appropriately.

Dietary Supplements: Estimates are that up to 150 million Americans consume dietary supplements regularly in order to maintain or improve their healthy lifestyles. These products, defined as vitamins, minerals, herbs and other botanicals, amino acids, or other dietary substances used to supplement the diet, are regulated under DSHEA, which set up the regulatory framework governing how these products are sold in the United States. Generally, under this law, ingredients in supplements marketed in the United States prior to October 15, 1994 are "grandfathered," that is, they may continue to be marketed in products without notification to or review by the agency prior to marketing. Also under DSHEA, most new ingredients are subject to a pre-notification system. The manufacturer of any supplement which contains a dietary ingredient not sold in the United States prior to October 15, 1994 can only sell that product if either the ingredient has been present in the food supply in the same form in which it is sold, or there is evidence that the ingredient is reasonably expected to be safe and the manufacturer provides evidence of that safety to the Secretary of Health and Human Services 75 days prior to marketing.

Critics of the regulatory scheme laid out by DSHEA argue that all, or at least some, dietary supplement products or ingredients (such as stimulants) should be subject to pre-marketing approval by the government. When approving DSHEA, this committee and later the Congress rejected such a regulatory system given the history of safe use of the majority of supplement products and the inherent cost of any pre-approval marketing requirement. The committee is not reconsidering that decision with this legislation.

In 2003, the FDA announced a new system to track adverse incidents associated with the use of foods, dietary supplements and cosmetics. The agency noted that determining the cause of such in-

cidents and helping to prevent their recurrence was the focus of the Center for Food Safety and Nutrition's (CFSAN's) new Adverse Event Reporting System or "CAERS." CAERS became part of an agencywide effort using information-gathering, data management and collaboration with health care institutions to improve the government's response to problems with products such as medical devices, vaccines, blood products, radiation-emitting products and drugs for animals. In a letter to stakeholders announcing the CAERS, CFSAN noted that the agency "will use the CAERS system as a monitoring tool to identify potential public health issues that may be associated with the use of a particular product already in the marketplace. Information gathered in CAERS will also assist FDA in the formulation and dissemination of CFSAN's post-marketing policies and procedures."

Over-the-Counter Drugs: Under current law, a nonprescription drug can be marketed in one of two ways. First, drugs previously sold by prescription may be sold over-the-counter if the FDA approves the "switch" through a New Drug Application (NDA). These drugs were subject to adverse event reporting when they had prescription status, and continue to be subject to those requirements as non-prescription drugs. In addition, drugs may be sold over-the-counter if the FDA has found them to be Generally Recognized as Safe and Effective (GRAS/GRAE). OTC drugs in this category must be manufactured, labeled, and marketed according to the monographs (regulations) promulgated by FDA. Although monographed OTC drugs are not currently required to file adverse event reports, many companies file AERs on a voluntary basis.

Monographed OTC drugs, as is true of other OTC drugs, have a very high margin of safety and most have been on the market for decades. They have been thoroughly reviewed by FDA for safety and effectiveness since the OTC drug review began in 1972, and they are manufactured, labeled, and marketed according to regulations established by the agency. Including monographed OTC drugs in FDA's adverse event reporting system provides consumers with additional assurance of OTC safety and enhances FDA's ability to ensure the public health.

The Dietary Supplement and Nonprescription Drug Consumer Protection Act builds on the CAERS by requiring that manufacturers of dietary supplements and now all non-prescription drugs provide to the FDA on an expedited basis any reports they receive of serious adverse events associated with the use of their products. This new reporting system will enhance the agency's effort to identify potential public health issues associated with the use of these products, and will enable the government, manufacturers, and retailers to respond more quickly to problems which may be identified. A new, comprehensive system will also serve to enhance the public's confidence in the products they purchase, since there will be greater government monitoring of serious problems.

III. Legislative History and Committee Action

Several years after the enactment of DSHEA, Congressional attention began to focus on how the Food and Drug Administration had implemented the law. There are concerns both that the agency has not implemented the law with sufficient vigor, and that the law makes it too difficult for the agency to act to protect public

health. For example, almost 12 years after the enactment of DSHEA, the FDA has yet to finalize the Good Manufacturing Practice (GMP) regulations authorized by the 1994 law. The committee encourages FDA to act quickly to finalize a GMP regulation for supplements, which would improve the quality and purity of dietary supplements. It should be noted that FDA has taken action against products that arguably could not have been sold in the first place if strong GMPs had been promulgated.

FDA has taken some enforcement actions against products that are clearly violative of the law's requirements for labeling and contents, such as products that contained undeclared active ingredients of prescription drugs, or misidentified herbal ingredients. In addition, Congress has stepped in to assist with other issues. Congress increased funding for FDA's actions to implement DSHEA. It approved legislation to make steroid precursor products illegal through the Controlled Substances Act, making these products the responsibility of the Drug Enforcement Agency, not the FDA. It also added new funding to expand the CAERS, and it began to consider proposals to require adverse event reporting for supplement products.

In February of 2004 the agency announced that it would remove from the market products containing ephedrine alkaloids, based on its review of evidence about ephedra's pharmacology, reports in the scientific literature, adverse event reports, including some of extremely serious adverse events, a report by the RAND Corporation, and thousands of public comments. A significant number of these adverse event reports had not been previously made available to the FDA.

On March 26, 2003, Senator Richard Durbin introduced S. 722, which would have amended the Federal Food, Drug, and Cosmetic Act to require, among other things, each manufacturer of a dietary supplement and each packer or distributor of a supplement the name of which appears on the labeling, to report serious adverse experiences to the Secretary of Health and Human Services and to investigate such occurrences. In June of the following year, Senator Durbin proposed an amendment (S.A. 3225) to S. 2400, the defense authorization bill, that would have precluded sale of stimulant products on military installations unless the manufacturer of the dietary supplement submitted any report of a serious adverse health experience to the Secretary of Health and Human Services.

On June 21, 2004, Senators Tom Harkin and Orrin Hatch filed an amendment to S.A. 3225, urging that the FDA make it a priority to implement fully and effectively the DSHEA, issue within 6 months a plan for mandatory reporting of serious adverse events occurring as a result of the ingestion of any dietary supplement or over-the-counter drug, and provide adequate resources for the effective oversight of dietary supplements and for sound scientific research on those products. After debate on these amendments, the three Senators agreed to withdraw their amendments and begin discussions of how to craft a serious adverse event reporting system.

On June 21, 2006, Senators Hatch, Durbin, Harkin, Enzi and Kennedy introduced S. 3546, the culmination of discussions which began in the summer of 2004 and which were expanded and intensified over the course of 2005 and early 2006. The bill was consid-

ered by the Committee on Health, Education, Labor, and Pensions on June 28, 2006 and ordered reported favorably with a Hatch amendment in the nature of a substitute. The substitute amendment, cosponsored by Senators Harkin, Enzi, and Kennedy, contained the language of S. 3546 as introduced, with the addition of an amendment clarifying the FDA's authority under section 801 of the Federal Food, Drug and Cosmetic Act with respect to foreign manufacturers of supplements.

IV. Explanation of Bill and Committee Views

Explanation of the Bill—The Dietary Supplement and Nonprescription Drug Consumer Protection Act sets up two parallel reporting systems, one for non-prescription drugs and the other for dietary supplements. Both programs are mandatory for the manufacturers, packers or distributors of the products, and require reporting of serious adverse events to the Food and Drug Administration. Serious adverse events are defined as those that result in death, a life-threatening experience, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect. In addition, a serious adverse event could be one that requires, based on reasonable medical judgment, a medical or surgical intervention to prevent the serious outcomes outlined above. These definitions are based upon those contained in the FDA's current Safety Information and Adverse Event Reporting Program (MedWatch).

The manufacturer, packer or distributor of the supplement or non-prescription drug must submit through the MedWatch form any serious adverse event report it receives and a copy of the labeling for the product to the Food and Drug Administration within 15 business days after the report is received. Consumers may provide reports to these responsible persons by phone through a number identified on the packaging or in writing if an address is printed on the label. Further, if any additional health-related information about the serious event is provided to the responsible person within 1 year of the initial report, that information must be forwarded to the FDA within 15 business days after it is received. Through notice and comment rulemaking, the Secretary may establish an exception to this reporting if he determines it would not have an adverse effect on public health. The Secretary is authorized to modify the MedWatch form if necessary.

The bill also imposes new requirements for records retention. The responsible person must maintain records of any adverse report it receives, whether serious or not, for 6 years. Officers or employees of the Department of Health and Human Services who have appropriate credentials and who are designated by the Secretary may have access to these records, consistent with inspections under section 704 of the FFDCA. Both the protections of the Privacy Act of 1974 and the Freedom of Information Act against unwarranted release of personal information would apply to these records and reports sent to FDA.

Finally, the bill contains several miscellaneous provisions. One provision ensures consistency at all level of government in mandatory adverse event reporting for nonprescription drugs or dietary supplements. Another provision authorizes the appropriation of "such sums" as may be necessary to carry out its provisions. The

general effective date of these amendments to the FFDCA will be 1 year after enactment, although any labeling changes that may be required will take effect after another year.

In summary, the bill contains five major provisions. First, it requires manufacturers and distributors of dietary supplements and OTC drugs to report all serious adverse events to FDA.

Second, the committee has limited the reporting requirement to the information FDA really needs: reports of death; a life-threatening experience; hospitalization; a persistent or significant disability or incapacity; a congenital anomaly or birth defect. In limiting the reporting system to serious events only, the committee recognizes that any broader reporting system could overburden manufacturers, consumers and the agency alike, generating information that may not be useful to the public health system at tremendous cost to all involved.

Third, the bill recognizes the need for reports to be accurate and valid. It does so in two ways—by prohibiting false reporting, and by authorizing the FDA to issue guidance on the information that is needed for a report to be deemed complete.

Fourth, S. 3546 sets a 15-day timeframe for responsible persons to submit the serious reports they receive to the FDA. Further, it requires that manufacturers keep for 6 years records related to all adverse events reports they receive, for both serious and non-serious events, and it allows the FDA to inspect these records.

Fifth, the new Federal reporting requirement would supersede state reporting requirements. States would still work closely with FDA on safety issues, and voluntary programs like Poison Control Centers would not be affected. FDA may share information and adverse event reports with States through memoranda of understanding.

In sum, the bill embodies three key principles: (1) While the majority of OTC drugs and supplements are safe, if serious problems arise, FDA should be informed—and promptly; (2) Safety information is prioritized. The most important safety information for FDA to receive is reports of serious adverse events, such as deaths or hospitalizations; and (3) Access to covered products is preserved. This bill will not affect consumer access to over-the-counter drugs or dietary supplements at all. But it will give consumers greater assurance that public health officials are on top of emerging, serious safety problems so they can take immediate, appropriate action.

Committee Views—Following are the committee's views on provisions contained within S. 3546:

Definition of Adverse Event: S. 3546 prescribes a strict definition of what constitutes a "serious" adverse event, including events that result in death or are life threatening, require hospitalization, or result in a birth defect or a persistent or significant disability. A serious adverse event could also include a case in which medical or surgical intervention is required to prevent any of the above.

The committee emphasizes that adverse events are communications from consumers regarding events that may be associated with the use of a dietary supplement or nonprescription drug. The fact of a report of an adverse event is not determinative that the event occurred or that the event was caused by a consumer's use of the product.

The definition of "serious adverse event" is modeled on nearly identical language for adverse experiences associated with drugs that appears in 21 CFR 310.305(b). The committee rejects any notion that use in the bill of a definition of "serious adverse event" modeled on a drug regulation definition "turns dietary supplements into drugs." Rather, the intent of this provision is to bring dietary supplements into the mainstream of products regulated by FDA with respect to reporting potential safety problems. After a great deal of examination, the committee concluded that the definition of "serious adverse event" now being used for drugs was equally useful as applied to adverse event reporting for dietary supplements and OTC drugs. The use of this definition does not subject dietary supplements to premarket approval, which is the major regulatory difference between a drug and a supplement.

A question has been raised about cases in which the responsible person may not agree with the reporter about the seriousness of an event. The committee cautions that the intent of these new systems is to alert officials about emerging problems with a product. As with current voluntary and mandatory reporting systems at the FDA, these new systems are designed to generate signals which require further evaluation. If the manufacturer, packer, or distributor receives a report from a consumer who believes he or she has experienced a serious adverse event consistent with the definition above, it is the responsibility of the entity taking the report to forward that report to the FDA whether or not the reporter sought medical care or otherwise had proof of a serious adverse event. Indeed, the committee notes that the MedWatch form, which the reporter must use under S. 3546, explicitly directs consumers to "Report, even if you're not certain the product caused the event" or "you don't have all the details." As the bill makes clear, a reporter may include additional information.

MedWatch Form: The committee has included authority for the Secretary to modify the MedWatch form if he believes it is not appropriate for reporting serious adverse events associated with the use of OTC drugs or dietary supplements. While there is no requirement that he do so, the Secretary is encouraged to entertain public comment before a new form, if any, is finalized. The committee urges that the Secretary undertake an examination of the utility of the MedWatch form for such reporting as quickly as possible so that implementation of the new law is neither disrupted nor delayed. The committee takes note that some representatives of the dietary supplement industry believe the MedWatch form needs to be revised for appropriate application to supplements, particularly with respect to Section 7, "Other Relevant History Including Preexisting Medical Conditions", and Section 10, "Concomitant Medical Products and Therapy Dates."

Further, it is the committee's strong view that the industries affected by S. 3546 should undertake as quickly as possible training for their staff so that they are aware of their surveillance, investigation and reporting duties.

Contracting of Reporting Obligation: The committee is aware of concerns that parties responsible for reporting have expressed they may not have the expertise to determine if an adverse event falls within the definition of "serious". The committee recognizes that many manufacturers have indicated they will contract their report-

ing function to a third party which has greater medical expertise. S. 3546 allows such contracting, with the understanding that the manufacturer, packer or distributor whose name appears on the label of the product still maintains ultimate responsibility for reporting under the law.

For those responsible persons who wish more assistance in determining the conditions that would trigger the "serious" adverse event definition, the committee has asked that the FDA provide guidance to help determine what events constitute "serious adverse events" within the definition included in this legislation.

Completeness of Reports Submitted: For the new serious adverse event reporting systems to be useful, reports submitted must be complete, accurate, and non-duplicative. In drafting S. 3546, the committee balanced two competing goals—the need to ensure as broad a reporting as possible of any serious adverse events against the cognizance that incomplete, false or duplicative reports could be harmful and costly to manufacturers, the FDA, and the public health. The committee intends to monitor this situation to ensure that the number of reports the agency receives is not inflated by incomplete reports that do not yield useful information. Further, it is the committee's view that the FDA should not compile any statistics about serious adverse event reports received which include numbers of incomplete reports.

While the committee appreciates the concerns of manufacturers that incomplete reports could indicate a less-than-serious report is being made, it is also important to note that there could be many reasons leading to an incomplete report, some of which in no way demean the validity of the report.

FDA's current guidance for mandatory adverse event reporting may be helpful in this discussion. In its Draft Guidance for Industry: Postmarketing Safety Reporting for Human Drug and Biological Products, Including Vaccines (March, 2001), the FDA indicates that four things are requisite of minimum knowledge necessary to submit a report to the agency. These are: an identifiable patient; an identifiable reporter; a suspect drug or biological product; and an adverse experience or fatal outcome suspected to be due to the suspect drug or biological product. This guidance makes clear that the word "identifiable" is essentially synonymous with an "individual," as opposed to a vague report such as "some patients got a rash." In addition, this guidance does not require that the reporter share contact information, given that some reporters may wish to remain anonymous based on privacy or other concerns.

Recognizing both the need to make certain that reports are valid and FDA's substantial experience in administering adverse event reporting systems as referenced above, the committee-approved bill includes a provision requiring the Secretary of Health and Human Services to issue guidance on the minimum data elements that should be included in any serious adverse event reports submitted under the two new systems authorized by S. 3546. Since it is important that responsible persons understand the information that must be included in any report to be submitted, the bill requires that the agency issue this guidance no later than 9 months after enactment.

Label Requirements: Under S. 3546, a dietary supplement or nonprescription drug marketed in the United States is misbranded

unless the label of the product includes an address or phone number through which the responsible person can receive a report of a serious adverse event with the product. The legislation does not require the label to make any statement other than providing the address or phone number. However, the committee expects that if a company chooses to make a statement on the label about the address or phone number, that such statement would conform to all requirements of the FFDCA.

In addition, the bill requires that the responsible person making a report include a copy of the label on or within the retail packaging of the dietary supplement or nonprescription drug. The actual label is not required to be submitted.

The committee recognizes that on occasion it may not be possible to ascertain the exact label of the product which the subject of the report used. In such cases, to be in compliance with the act, the responsible person may submit copies of the label most likely viewed by the subject of the report, or may submit multiple labels for those products most likely to be associated with the report. If the product used cannot be identified, the responsible person would not be expected to submit any labeling.

Release of Reports: The Food and Drug Administration has advised the committee that it has no plans for a Web site which would release the serious adverse event reports it receives for nonprescription drugs and/or dietary supplements. The committee requests that the agency notify the Congress prior to changing this policy if it intends to post reports required by this legislation on a publicly-available website.

Multiple Reports of the Same Incident: In drafting S. 3546, the committee believed that the new reporting systems must be designed to encourage a broad reporting of all serious adverse events so that the government has early information about potential health problems associated with either non-prescription drugs or dietary supplements. That being said, the committee was also sympathetic to concerns expressed that the potential for multiple reporting of the same event could artificially inflate the numbers of reports associated with a product. Consequently, S. 3546 includes an explicit requirement that the Secretary must develop systems to ensure consolidation into a single report of both duplicate reports of a serious adverse event, and duplicate reports of additional medical information related to that event.

Ongoing Reporting Obligation: The bill requires the responsible person to submit to the Secretary within 15 business days additional information related to the serious adverse event that is received by the entity. This information should be provided as soon as is practicable before that time. Due to concerns expressed by reporting parties about the significant burden posed by this ongoing requirement, S. 3546 as approved by the committee limits this responsibility so that the manufacturer, packer or distributor must only report additional information received within 1 year of the initial report. The committee notes that the application of this provision is limited to reports of additional medical information the responsible person receives from an individual reporter or person acting on behalf of the reporter. Material related to litigation about the event does not fall within the scope of this reporting requirement.

In the committee's view, new medical information or supplemental information that is submitted should become part of the original report, including information that would either bolster or negate the credibility of the initial report. Thus, when a report is provided to a third party by the Secretary, the complete report (including the new and supplemental information) should be included.

Records Retention: Sections 760(e) and 761(e) require that the responsible person, that is, the manufacturer, packer or distributor, maintain records related to each report of an adverse event received by that person for a period of 6 years from the time that the report is received by the responsible person. These records should be maintained at a location which allows government inspectors access on a timely basis. The records required to be kept under these provisions include all reports of adverse events and serious adverse events received by the responsible person, the records containing the submission by the responsible person of serious adverse event reports to the Secretary, the records containing the submission to the Secretary of new medical information related to serious adverse event reports, and records containing communications by the responsible person with any person or persons reporting any adverse event to the responsible person. These records must be maintained regardless of the source of the report, and regardless of any determination by the responsible person that the adverse event was caused by, or associated with, the product.

Responsibility of Retailers: Under S. 3546, in general, the manufacturer, packer or distributor of a covered product whose name appears on the label is responsible for making reports to the Secretary of serious adverse events associated with the use of their products. A retailer whose name appears on the label as a distributor may, by agreement, authorize the manufacturer or packer of the product (generally referred to as a "private label product") to submit the required reports so long as the retailer directs to the manufacturer or packer all adverse events associated with the product's use that are reported to him through the address or telephone number required in the bill.

Thus, retailers who do not have such private label products, that is, products bearing the retailer's name, do not have any reporting obligation under S. 3546.

Retailers who have private label products will have to make a decision about who will be the responsible person for the purposes of reporting. Such retailers will have to choose either to assign the reporting responsibility by agreement to the manufacturer of their private label products, or report the serious adverse events themselves. In the latter case only, the retailer would be considered a responsible person and would need to comply with the record-keeping requirements contained in S. 3546.

If a retailer who chooses to act as a distributor of a private label product receives a serious adverse event report through the address or telephone number described in section 403(y) or in section 502(x), the retailer must direct the report to the FDA, or if the retailer has an agreement under which the manufacturer must submit such reports to the FDA, to the manufacturer. In any other cases in which a customer contacts a store and informs the retailer of an adverse event with a private label product, the retailer should

provide the phone number or address of that manufacturer to the customer.

Penalties for False Reporting: For the integrity of the new reporting systems to be maintained, it is important that reports which are filed be truthful and accurately capture the facts associated with an actual incident. The committee is aware of concerns that false reports could be filed in an effort for one entity to gain a competitive advantage over another, or for unscrupulous individuals to exact an unwarranted monetary settlement. Similarly, it is important that the government receive the most accurate information. For that reason, included within S. 3546 are penalties intended to be a strong deterrent to false reporting.

Specifically, the bill makes it illegal to falsify a report to be provided to the manufacturer, packer or distributor. It also makes it illegal for a manufacturer, packer or distributor to falsify a report to be submitted to the government. The committee wishes to underscore that the penalties do not apply to the mere inadvertent submission of a report in error, but rather to a report that has been deliberately falsified. The committee recognizes that it is important for the information provided to the FDA to be accurate in order for the new reporting system to work appropriately.

The bill makes non-compliance a prohibited act under the Federal Food, Drug and Cosmetic Act, so that a violation by a person can trigger an injunction or criminal penalties. If there is a criminal conviction, a fine can be imposed.

The bill also deems a product misbranded if it is not labeled with an address or phone number to which consumers can report a serious adverse event. Distribution of a misbranded product is also a prohibited act, for which an injunction or criminal penalties could apply. There is also seizure authority in this case.

Electronic Reporting: Parties who will be responsible for reporting purposes under S. 3546 have indicated that they are interested in submitting reports electronically. Officials at the Food and Drug Administration have indicated their interest in moving eventually toward e-reporting of adverse events for all products subject to mandatory or voluntary reporting. In the absence of the agency developing such a system, the committee notes that responsible persons may file reports electronically using the e-MedWatch form.

Similarly, the committee is aware that consumers may wish to file serious adverse event reports with a responsible person electronically via the internet. Therefore, it is the committee's intent that responsible persons may provide on the product label an email address to which reports may be made, provided such email address is in addition to the phone number or address required under the language of S. 3546.

Duty to Investigate Reports: Many people, including many members of this committee, believe that, for decades before the enactment of DSHEA, the Food and Drug Administration displayed an animosity toward dietary supplements. Indeed, in the Advance Notice of Proposed Rulemaking (ANPR) published in the Federal Register of June 18, 1993 (58 F.R. 33960–33751), the agency in effect proposed subjecting vitamins, minerals, herbs, and amino acids and other similar dietary ingredients to new drug or food additive status, or potency limits on product dosages. The ensuing public out-

cry compelled the Congress to withdraw that ANPR legislatively and pass DSHEA.

The committee wishes to note that, although the FDA has been slow to implement certain aspects of DSHEA, most notably in its lack of publishing final Good Manufacturing Practice regulations, the agency has made significant progress in responsible regulation of dietary supplements. In particular, the committee notes the outstanding quality and accuracy of information about DSHEA contained in the FDA's Web site, and the cooperation of agency officials who coordinate with the Congress on supplement-related matters.

Given the agency's history with dietary supplements in the 1960s, 1970s and 1980s, however, the committee understands the motivation of some who suggest either that the new AER system should be limited to cases in which the supplements caused the adverse event (as opposed to being associated with the event) or that the FDA must investigate any event to determine if it were caused by the supplement before the report is "accepted" by the FDA.

Although the committee understood the motivation for these suggestions and took these comments very seriously, it ultimately concluded they were not warranted. First, as noted above, there is not sufficient evidence to indicate that the FDA will mishandle or distort the new system. Second, the committee concluded that there would be problems inherent in requiring the FDA to prove the supplement or OTC drug caused the serious adverse event prior to accepting the report. Even if a system for proving the causality could be determined and agreed upon, proving that causality could be very costly and entail long delays in reporting, depriving public health officials of the valuable sentinel information inherent in a report. The committee notes that the intent of the new system is not to determine causality, but rather to provide the government with information about possible problems associated with the use of a supplement or OTC drug.

Conversely, the committee is aware of concerns that possible litigation may ensue from the fact that a report was filed, and that the report could be construed as an admission that the product "caused" the serious event. In response, the committee took great pains to make clear that the mere filing of a report will in no way indicate causation of the serious adverse event. To underscore that point, language is included in S. 3546 indicating that the submission of an adverse event report in compliance with the bill's requirements shall not be construed as an admission that the nonprescription drug or dietary supplement involved caused or contributed to the adverse event or otherwise caused or contributed to a death, serious injury or serious illness.

Homeopathic Remedies and Traditional Chinese Medicines: The committee is aware that some have suggested "homeopathic remedies" and "traditional Chinese medicines" should be included in the mandatory reporting system required by S. 3546. The committee believes there is no need for an explicit inclusion of homeopathic remedies in this legislation. These products are regulated either as drugs under section 201(g)(1)(A) of the Federal Food, Drug, and Cosmetic Act, which governs "articles referenced in the official Homeopathic Pharmacopeia of the United States," or as non-prescription drugs, drugs that are not subject to section 503(b) or are

not approved under section 505 of the Act. In the first instance, drugs are already covered by a mandatory adverse event reporting system, and in the second instance, non-prescription drugs will be covered by S. 3546.

There is no explicit reference to "Traditional Chinese Medicines," or as they are sometimes called "Traditional Asian Medicines," in Federal food and drug law. However, herbal products that are used in traditional Chinese medicine and that are marketed as supplements would be covered by S. 3546.

Importation of Products When Foreign Manufacturer is not in Compliance: During the drafting of S. 3546, three concerns were raised about the Food and Drug Administration's ability to take action against imported products if the foreign manufacturer were not in compliance with the reporting requirements of this act. The current section 801 of the FFDCA is inadequate to address this situation, since it only applies to products that appear to be misbranded or adulterated, not to situations in which the foreign manufacturer fails to comply with the new reporting system. The new section 5 of S. 3546 added with the substitute approved by the committee will address this situation.

The first concern relates to a case in which a foreign manufacturer's product arrives at port and does not properly contain the name and contact information on the label. That case is addressed by the provisions of S. 3546 stating that the label must contain and name and address or telephone number or else it is misbranded. In that case, the FDA has authority to refuse admission based on its authority under section 403 of the Federal Food, Drug and Cosmetic Act.

The second concern is whether the language amending section 801 in S. 3546 applies to finished products only, or whether it includes raw materials. Because the plain language of the bill refers to an "article that is subject to a requirement under section 760 or 761," it is clear that it applies only to finished products and not raw materials or dietary ingredients, which are not subject to section 760 or 761.

The third instance, in which the imported product itself may appear to comply with the law, but the manufacturer has not filed adverse event reports in the past, for this or other products, gave rise to the new language included in the committee substitute.

Section 5 amends section 801 of the FFDCA so that an imported OTC drug or a dietary supplement shall be refused admission if the FDA has credible information indicating that the responsible person has not complied with its reporting responsibilities under section 760 or 761. To rectify this situation, the responsible person, or the owner or consignee on behalf of the responsible person, may seek authorization to act to ensure that he is in compliance. If FDA grants the application, it will authorize the applicant to perform the actions specified in the authorization upon the filing of a bond, under the supervision of an officer or employee of the FDA. The OTC drug or dietary supplement may be delivered to the owner or consignee upon the execution of a good and sufficient bond, and FDA's costs of supervision must be paid by the owner or consignee.

There is no requirement in this legislation that the FDA certify for compliance each import admitted into this country under section 801.

CAERS System: This legislation, when enacted, will supersede that portion of the Center for Food Safety and Nutrition's (CFSAN's) Adverse Event Reporting System or "CAERS" which is related to voluntary reporting of dietary supplement adverse events. This should both obviate duplicative programs and reduce costs for the agency after the initial implementation is completed.

V. Cost Estimate

Due to time constraints the Congressional Budget Office estimate was not included in the report. When received by the committee, it will appear in the Congressional Record at a later time.

VI. Application of Law to the Legislative Branch

S. 3546 amends the Federal Food, Drug and Cosmetic Act to provide a system of mandatory serious adverse event reporting for problems associated with non-prescription drugs and dietary supplements. As such, it has no application to the legislative branch.

VII. Regulatory Impact Statement

Pursuant to the requirements of paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has determined that the bill will not have a significant regulatory impact.

VIII. Section-by-Section Analysis

Section 1. Short title

Provides that the bill may be cited as the "Dietary Supplement and Nonprescription Drug Consumer Protection Act".

Section 2. Serious adverse event reporting for nonprescription drugs

Subsection (a) adds a new section 760 to the Federal Food, Drug, and Cosmetic Act to require serious adverse event reporting for nonprescription drugs. The new section 760(a) provides definitions for "adverse event," "nonprescription drug," "serious adverse event," and "serious adverse event report."

First, "adverse event" is defined as a health-related event associated with the use of a nonprescription drug that is adverse. Such events include those occurring from accidental or intentional overdose, drug abuse, drug withdrawal, or failure of expected pharmacological action.

Second, for purposes of this act, "nonprescription drug" means a drug that does not require a prescription for use (an over-the-counter drug). It does not include an OTC drug approved under section 505 of the FFDCA, because adverse event reporting is already required for such drugs.

Third, "serious adverse event" means an adverse event that results in death, a life-threatening experience, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect, or that requires, based on reasonable medical judgment, medical or surgical intervention to prevent one of these outcomes.

Fourth, "serious adverse event report" is a report to the Food and Drug Administration (FDA) about a serious adverse event, as required under the bill.

Section 760(b) requires the manufacturer, packer, or distributor whose name appears on the label of an OTC drug (referred to as the "responsible person") marketed in the United States to submit to the FDA a report received about a serious adverse event with the drug from use in the United States, along with a copy of the label of the OTC drug.

Section 760(c) requires submission to FDA of a serious adverse event report, or new medical information received within a year of receipt of the initial report, within 15 days of receipt. FDA must develop a system to insure that duplicate reports of a serious adverse event, and new medical information, are consolidated into a single report. FDA may create an exemption from this requirement after comment from interested parties when it determines there would be no adverse effect on public health.

Section 760(d) requires serious adverse event reports to be submitted using the FDA's MedWatch form, which the Secretary is authorized to modify, accompanied by any additional information.

Section 760(e) requires the responsible person to maintain records related to adverse events for 6 years, and permits authorized persons from the FDA to inspect the records.

Section 760(f) provides that a report of an adverse event may include a statement that the report is not an admission that the OTC drug caused or contributed to the adverse event, and that a report may not be publicly disclosed unless information that identifies the person affected is redacted.

Section 760(g) states that submission of an adverse event to FDA shall not be construed as an admission that the OTC drug caused or contributed to the adverse event.

Section 760(h) preempts State and local mandatory adverse event reporting requirements that are different from or in addition to the requirement in this section. It also ensures that FDA may share adverse event reports with appropriate State and local officials under a memorandum of understanding with the State or locality. States and localities may not disclose personally identifiable information in reports they receive from the FDA pursuant to State or local disclosure laws or otherwise, unless the State or locality receives the written consent of both the FDA and the person who submitted the information to the FDA. States and localities may not use safety reports received from FDA in way that is inconsistent with subsection (g) or section 756 of the FFDCA.

Section 760(i) authorizes the appropriation of necessary funds to implement the section.

Subsection (b) allows the FDA to modify the requirements of section 760 by rulemaking to maintain consistency with international harmonization efforts.

Subsection (c) amends section 301 of the FFDCA to make it a prohibited act under the FFDCA, and so subject to injunction or criminal prosecution, to fail to maintain or provide access to records, or make reports, as required under section 760.

Subsection (d) amends section 502 of the FFDCA to require the responsible person to include on the label of an OTC drug an address or telephone number through which serious adverse events can be reported to the responsible person.

Subsection (e) makes section 760 effective 1 year after enactment, and the amendment of section 502 under subsection (d) ap-

plies to OTC drugs labeled on or after the date 1 year after enactment. FDA is required to issue guidance on the minimum data elements that should be included in a serious adverse event report no later than 270 days after the date of enactment.

Section 3. Serious adverse event reporting for dietary supplements

Subsection (a) adds a new section 761 to the FDCA to require serious adverse event reporting for dietary supplements.

Section 761(a) provides definitions for "adverse event," serious adverse event," and "serious adverse event report."

First, "adverse event" is defined to mean a health-related event associated with the use of a dietary supplement that is adverse.

Second, "serious adverse event" is defined to mean an adverse event that results in death, a life-threatening experience, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect, or that requires, based on reasonable medical judgment, medical or surgical intervention to prevent one of these outcomes.

Third, "serious adverse event report" is a report to the FDA about a serious adverse event, as required under the bill.

Section 761(b) requires the manufacturer, packer, or distributor whose name appears on the label of a dietary supplement (referred to as the "responsible person") marketed in the United States to submit to the FDA a report received about a serious adverse event with the dietary supplement from use in the United States, along with a copy of the label on or within the retail packaging of the supplement. It allows a retailer whose name appears on the label to authorize the manufacturer or packer of the supplement to submit the reports to FDA if it notifies the manufacturer or packer of the reports it receives.

Section 761(c) requires submission to FDA of a serious adverse event report, or new medical information received within a year of receipt of the initial report, within 15 days of receipt. FDA must develop a system to insure that duplicate reports of a serious adverse event, and new medical information, are consolidated into a single report. FDA may create an exemption from this requirement after comment from interested parties when it determines there would be no adverse effect on public health.

Section 761(d) requires serious adverse event reports to be submitted using the FDA's MedWatch form, which the Secretary may modify, along with additional information.

Section 761(e) requires the responsible person to maintain records related to adverse events for 6 years, and permits authorized persons from the FDA to inspect the records.

Section 761(f) provides that a report of an adverse event may include a statement that the report is not an admission that the dietary supplement caused or contributed to the reported adverse event, and that the reports may not be publicly disclosed unless information that could identify the person affected is redacted.

Section 761(g) states that submission of an adverse event to FDA shall not be construed as an admission that the dietary supplement caused or contributed to the adverse event.

Section 761(h) preempts State and local mandatory adverse event reporting requirements that are different from or in addition to the requirement in the bill. It also ensures that FDA may share

adverse event reports with appropriate State and local officials under a memorandum of understanding with the State or locality. States and localities may not disclose personally identifiable information in reports they receive from the FDA pursuant to State or local disclosure laws or otherwise, unless the State or locality receives the written consent of both the FDA and the person who submitted the information to the FDA. States and localities may not use safety reports received from FDA in way that is inconsistent with subsection (g) or section 756 of the FFDCA.

Section 761(i) authorizes the appropriation of necessary funds to implement the section.

Subsection (b) amends section 301 of the FFDCA to make it a prohibited act under the FFDCA, and so subject to injunction or criminal prosecution, to fail to maintain or provide access to records, or make reports, as required under section 761.

Subsection (c) amends section 403 of the FFDCA to require the responsible person to include on the label of a dietary supplement an address or telephone number through which serious adverse events can be reported to the responsible person.

Subsection (d) makes section 761 effective 1 year after enactment, and the amendment of section 403 under subsection (c) applies to dietary supplements labeled on or after the date 1 year after enactment. FDA is required to issue guidance on the minimum data elements that should be included in a serious adverse event report no later than 270 days after the date of enactment.

Section 4. Prohibition of falsification of reports

Section 4 amends section 301 of the FFDCA to make it a prohibited act under the FFDCA, and so subject to injunction or criminal prosecution, to falsify a report of a serious adverse event submitted to a responsible person under section 760 or 761, or to falsify a serious adverse event submitted to FDA under section 760 or 761.

Section 5. Importation of certain nonprescription drugs and dietary supplements

Section 5 amends section 801 of the FFDCA to say that an OTC drug or a dietary supplement subject to section 760 or 761, when being imported or offered for import, shall be refused admission if FDA has credible evidence or information indicating that the responsible person under section 760 or 761 has not complied with a requirement of either section with respect to an OTC drug or a dietary supplement. It permits the responsible person, or the owner or consignee on behalf of the responsible person, to submit an application for authorization to take actions to ensure the responsible person is in compliance with section 760 or 761, as the case may be. FDA must act on the application, and if FDA grants the application, authorize the applicant to perform the actions specified in the authorization upon the filing of a bond, under the supervision of an officer or employee of the FDA. The OTC drug or dietary supplement may be delivered to the owner or consignee upon the execution of a good and sufficient bond, and FDA's costs of supervision must be paid by the owner or consignee.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG AND COSMETIC ACT

* * * * * * *

PROHIBITED ACTS

SEC. 301. * * *
(a) * * *

* * * * * * *

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 416, 504, 564, 703**[**, or 704(a);**]** *704(a)***[**, or 760;**]***, 760, or 761;* or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 416, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i).,[2] 515(f), 519**[**, or 564**]***, 564***[**, or 760**]***, 760, or 761* or the refusal to permit access to or verification or copying of any such required record.

* * * * * * *

(z) * * *
(aa) * * *

* * * * * * *

(ii) The falsification of a report of a serious adverse event submitted to a responsible person (as defined under section 760 or 761) or the falsification of a serious adverse event report (as defined under section 760 or 761) submitted to the Secretary.

* * * * * * *

MISBRANDED FOOD

SEC. 403. * * *
(a) * * *

* * * * * * *

(x) * * *

* * * * * * *

(y) If it is a dietary supplement that is marketed in the United States, unless the label of such dietary supplement includes a domestic address or domestic phone number through which the responsible person (as described in section 761) may receive a report of a serious adverse event with such dietary supplement.

* * * * * * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. * * *

(a) * * *

* * * * * * *

(w) * * *

* * * * * * *

(x) If it is a nonprescription drug (as defined in section 760) that is marketed in the United States, unless the label of such drug includes a domestic address or domestic phone number through which the responsible person (as described in section 760) may receive a report of a serious adverse event (as defined in section 760) with such drug.

* * * * * * *

CHAPTER VII—GENERAL AUTHORITY

SUBCHAPTER A—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

* * * * * * *

SUBCHAPTER G—SAFETY REPORTS

* * * * * * *

Subchapter H—Serious Adverse Event Reports

SEC. 760. SERIOUS ADVERSE EVENT REPORTING FOR NON-PRESCRIPTION DRUGS.

(a) DEFINITIONS.—In this section:

(1) ADVERSE EVENT.—The term "adverse event" means any health-related event associated with the use of a nonprescription drug that is adverse, including—

(A) an event occurring from an overdose of the drug, whether accidental or intentional;

(B) an event occurring from abuse of the drug;

(C) an event occurring from withdrawal from the drug; and

(D) any failure of expected pharmacological action of the drug.

(2) NONPRESCRIPTION DRUG.—The term "non-prescription drug" means a drug that is—

(A) Not subject to section 503(b); and

(B) Not subject to approval in an application submitted under section 505.

(3) SERIOUS ADVERSE EVENT.—The term "serious adverse event" is an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity; or

(v) a congenital anomaly or birth defect; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(4) SERIOUS ADVERSE EVENT REPORT.—The term "serious adverse event report" means a report that is required to be submitted to the Secretary under subsection (b).

(b) REPORTING REQUIREMENT.—

(1) IN GENERAL.—The manufacturer, packer, or distributor whose name (pursuant to section 502(b)(1)) appears on the label of a nonprescription drug marketed in the United States (referred to in this section as the "responsible person" shall submit to the Secretary any report received of a serious adverse event associated with such drug when used in the United States, accompanied by a copy of the label on or within the retail package of such drug.

(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the nonprescription drug to submit the required reports for such drugs to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such drug that are reported to the retailer through the address or telephone number described in section 502(x).

(c) SUBMISSION OF REPORTS.—

(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report no later than 15 business days after the report is received through the address or phone number described in section 502(x).

(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

(4) EXEMPTION.—The Secretary, after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

(d) CONTENTS OF REPORTS.—Each serious adverse event report under this section shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for nonprescription drugs, and may be accompanied by additional information.

(e) MAINTENANCE AND INSPECTION OF RECORDS.—

(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

(2) RECORDS INSPECTION.—

(A) IN GENERAL.—The responsible person shall permit an authorized person to have access to records required to be

maintained under this section, during an inspection pursuant to section 704.

(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term "authorized person" means an officer or employee of the Department of Health and Human Services who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been duly designated by the Secretary to have access to the records required under this section.

(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntary submitted to the Secretary shall be considered to be—

(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the "Privacy Act of 1974" and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the "Freedom of Information Act", and shall not be publicly disclosed unless all personally identifiable information is redacted.

(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the non-prescription drug involved caused or contributed to the adverse event.

(h) PREEMPTION.—

(1) IN GENERAL.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for nonprescription drugs, that is different from, in addition to, or otherwise not identical to, this section.

(2) EFFECT OF SECTION.—

(A) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, shall not—

(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

(C) USE OF SAFETY REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.

* * * * * * *

SEC. 761. SERIOUS ADVERSE EVENT REPORTING ON DIETARY SUPPLEMENTS.

(a) DEFINITIONS.—In this section:

(1) ADVERSE EVENT.—The term "adverse event" means any health-related event associated with the use of a dietary supplement that is adverse.

(2) SERIOUS ADVERSE EVENT.—The term "serious adverse event" is an adverse event that—

(A) results in—

(i) death;

(ii) a life-threatening experience;

(iii) inpatient hospitalization;

(iv) a persistent or significant disability or incapacity; or

(v) a congential anomaly or birth defect; or

(B) requires, based on reasonable medical judgment, a medical or surgical intervention to prevent an outcome described under subparagraph (A).

(3) SERIOUS ADVERSE EVENT REPORT.—The term "serious adverse event report" means a report that is required to be submitted to the Secretary under subsection (b).

(b) REPORTING REQUIREMENT.—

(1) IN GENERAL.—The manufacturer, packer, or distributor of a dietary supplement whose name (pursuant to section 403(e)(1)) appears on the label of a dietary supplement marketed in the United States (referred to in this section as the "responsible person" shall submit to the Secretary any report received of a serious adverse event associated with such dietary supplement when used in the United States, accompanied by a copy of the label on or within the retail packaging of such dietary supplement.

(2) RETAILER.—A retailer whose name appears on the label described in paragraph (1) as a distributor may, by agreement, authorize the manufacturer or packer of the dietary supplement to submit the required reports for such dietary supplements to the Secretary so long as the retailer directs to the manufacturer or packer all adverse events associated with such dietary supplement that are reported to the retailer through the address or telephone number described in section 403(y).

(c) SUBMISSION OF REPORTS.—

(1) TIMING OF REPORTS.—The responsible person shall submit to the Secretary a serious adverse event report no later than 15

business days after the report is received through the address or phone number described in section 403(y).

(2) NEW MEDICAL INFORMATION.—The responsible person shall submit to the Secretary any new medical information, related to a submitted serious adverse event report that is received by the responsible person within 1 year of the initial report, no later than 15 business days after the new information is received by the responsible person.

(3) CONSOLIDATION OF REPORTS.—The Secretary shall develop systems to ensure that duplicate reports of, and new medical information related to, a serious adverse event shall be consolidated into a single report.

(4) EXEMPTION.—The Secretary after providing notice and an opportunity for comment from interested parties, may establish an exemption to the requirements under paragraphs (1) and (2) if the Secretary determines that such exemption would have no adverse effect on public health.

(d) CONTENTS OF REPORTS.—Each serious adverse event report under this seciton shall be submitted to the Secretary using the MedWatch form, which may be modified by the Secretary for dietary supplements, and may be accompanied by additional information.

(e) MAINTENANCE AND INSPECTION RECORDS.—

(1) MAINTENANCE.—The responsible person shall maintain records related to each report of an adverse event received by the responsible person for a period of 6 years.

(2) RECORDS INSPECTION.—

(A) IN GENERAL.—The responsible person shall permit an authorized person to have access to records required to be maintained under this section during an inspection pursuant to section 704.

(B) AUTHORIZED PERSON.—For purposes of this paragraph, the term "authorized person" means an officer or employee of the Department of Health and Human Services, who has—

(i) appropriate credentials, as determined by the Secretary; and

(ii) been duly designated by the Secretary to have access to the records required under this section.

(f) PROTECTED INFORMATION.—A serious adverse event report submitted to the Secretary under this section, including any new medical information submitted under subsection (c)(2), or an adverse event report voluntarily submitted to the Secretary shall be considered to be—

(1) a safety report under section 756 and may be accompanied by a statement, which shall be a part of any report that is released for public disclosure, that denies that the report or the records constitute an admission that the product involved caused or contributed to the adverse event; and

(2) a record about an individual under section 552a of title 5, United States Code (commonly referred to as the "Privacy Act of 1974" and a medical or similar file the disclosure of which would constitute a violation of section 552 of such title 5 (commonly referred to as the "Freedom of Information Act", and shall not be publicly disclosed unless all personally identifiable information is redacted.

(g) RULE OF CONSTRUCTION.—The submission of any adverse event report in compliance with this section shall not be construed as an admission that the dietary supplement involved caused or contributed to the adverse event.

(h) PREEMPTION.—

(1) IN GENERAL.—No State or local government shall establish or continue in effect any law, regulation, order, or other requirement, related to a mandatory system for adverse event reports for dietary supplements, that is different from, in addition to, or otherwise not identical to, this seciton.

(2) EFFECT OF SECTION.—

(A) IN GENERAL.—Nothing in this section shall affect the authority of the Secretary to provide adverse event reports and information to any health, food, or drug officer or employee of any State, territory, or political subdivision of a State or territory, under a memorandum of understanding between the Secretary and such State, territory, or political subdivision.

(B) PERSONALLY-IDENTIFIABLE INFORMATION.—Notwithstanding any other provision of law, personally-identifiable information in adverse event reports provided by the Secretary to any health, food, or drug officer or employee of an State, territory, or political subdivision of a State or territory, shall not—

(i) be made publicly available pursuant to any State or other law requiring disclosure of information or records; or

(ii) otherwise be disclosed or distributed to any party without the written consent of the Secretary and the person submitting such information to the Secretary.

(C) USE OF SAFETY REPORTS.—Nothing in this section shall permit a State, territory, or political subdivision of a State or territory, to use any safety report received from the Secretary in a manner inconsistent with subsection (g) or section 756.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.

* * * * * * *

CHAPTER VIII—IMPORTS AND EXPORTS

IMPORTS AND EXPORTS

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. The Secretary of Health and Human Services shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs or devices manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are im-

ported or offered for import into the United States, samples of such drugs or devices be delivered to the Secretary of Health and Human Services, with notice of such delivery to the owner or consignee, who may appear before the Secretary of Health and Human Services and have the right to introduce testimony. *If such article is subject to a requirement under section 760 or 761 and if the Secretary has credible evidence or information indicating that the responsible person (as defined in such section 760 or 761) has not complied with a requirement of such section 760 or 761 with respect to any such article, or has not allowed access to records described in such section 760 or 761, then such article shall be refused admission, except as provided in subsection (b) of this section.* If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions or, in the case of a device, the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of section 520(f), or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations. Clause (2) of the third sentence of this paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under the Controlled Substances Import and Export Act.

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health and Human Services that *(1)* an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic*, or (2) with respect to an article included within the provision of the fourth sentence of subsection (a), the responsible person (as defined in section 760 or 761) can take action that would assure that the responsible person is in compliance with section 760 or 761, as the case may be,* final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in the preceding provisions of this subsection, the Secretary may, in accordance with regulations, authorize the applicant, *or, with respect to clause (2), the responsible person,* to perform such relabeling or other action, specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization). All such relabeling or other action pursuant

to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health and Human Services designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

* * * * * * *

○