I

108TH CONGRESS
1ST SESSION

H. R. 1075

To amend the Federal Food, Drug, and Cosmetic Act with respect to dietary supplements containing natural or synthetic ephedrine group alkaloids, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 4, 2003

Mr. SWEENEY (for himself and Mr. WALDEN of Oregon) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to dietary supplements containing natural or synthetic ephedrine group alkaloids, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ephedra Public Protection Act''.

SEC. 2. REQUIREMENT OF PREMARKET APPROVAL FOR DIETARY SUPPLEMENTS CONTAINING EPHEDRINE GROUP ALKALOIDS; REPORTING OF SERIOUS ADVERSE EXPERIENCES.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended—

(1) in section 402(a)(2), by inserting after ''section 512; or'' the following: ''(D) if it is a dietary supplement that contains any ephedrine group alkaloids and is unsafe within the meaning of section 416; or''; and

(2) by adding at the end the following section:

''SEC. 416. EPHEDRINE GROUP ALKALOIDS.

''(a) REQUIREMENT OF PREMARKET APPROVAL.—A new ephedrine supplement shall be deemed unsafe for purposes of section 402(a)(2)(D) unless an approval of an application filed under subsection (b) is effective with respect to such supplement.

''(b) APPLICATION.—Any person may file with the Secretary an application with respect to a new ephedrine supplement. Not later than 180 days after the filing of the application, or such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall either—

''(1) issue an order under subsection (c) approving the application; or

''(2) issue an order refusing to approve the application, after providing the applicant notice of an opportunity for a hearing before the Secretary.

''(c) STANDARDS.—The Secretary shall approve an application under subsection (b) for a new ephedrine supplement if the application meets the criteria of the Secretary for demonstrating to the Secretary that the supplement does not present a significant or unreasonable risk of illness or injury—

''(1) under the conditions of use recommended or suggested in the labeling for the supplement; or

''(2) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.

''(d) REPORTING OF SERIOUS ADVERSE EXPERIENCES.—

''(1) IN GENERAL.—Each person who is a manufacturer of ephedrine supplements, or a packer or distributor of the supplements whose name appears on the labeling of the supplement, shall (with respect to such supplements manufactured, packed, or distributed by that person)—

"(A) investigate each claim of a serious adverse experience of which the person is aware in order to determine whether the claim is a documented incident;

"(B) investigate each documented incident of such an experience;

"(C) develop and implement written procedures for investigations of such claims and incidents; and

"(D) submit to the Secretary in accordance with paragraph (2) notifications and reports regarding such claims and incidents.

"(2) CERTAIN REQUIREMENTS.—

"(A) NOTIFICATION OF SECRETARY REGARDING DOCUMENTED INCIDENT.—As soon as possible but not later than 30 days after becoming aware of a claim of a serious adverse experience with respect to an ephedrine supplement, the applicable person under paragraph (1) shall determine whether the claim is a documented incident, and if the claim is such an incident, shall submit to the Secretary a notification of such fact. The notification shall include a copy of the current labeling for the supplement.

''(B) REPORT REGARDING RESULTS OF INVESTIGATION.—As soon as possible but not later than 60 days after identifying a documented incident of a serious adverse experience, the applicable person under paragraph (1) shall complete an investigation of the experience and submit to the Secretary a report describing the findings of the investigation, including a finding on whether the ephedrine supplement involved is a causal factor in such experience.

''(3) DUPLICATIVE REPORTS.—The Secretary may establish procedures to avoid duplicative reporting under paragraph (1) on an ephedrine supplement by the persons referred to in such paragraph with respect to such supplement, subject to the Secretary establishing requirements to ensure that the Secretary receives notifications and reports within the period of time specified in paragraph (2).

''(e) APPLICABILITY OF CERTAIN PROVISIONS.—In the case of new ephedrine supplements, this section applies in lieu of sections 402(f)(1)(A) and 402(f)(1)(B). In the case of any ephedrine supplement, the two sentences immediately following section 402(f)(1)(D) do not apply, and section 402(f)(2) does not apply.

''(f) DEFINITIONS.—

''(1) EPHEDRINE SUPPLEMENTS.—For purposes of this section:

''(A) The term 'ephedrine supplement' means a dietary supplement containing any ephedrine group alkaloids (as defined in section 201(nn)).

''(B) The term 'new ephedrine supplement' means a dietary supplement containing any new ephedrine group alkaloids (as defined in section 201(nn)).

''(2) SERIOUS ADVERSE EXPERIENCES.—For purpose of this section:

''(A)(i) The term 'adverse experience', with respect to an ephedrine supplement, means an adverse health-related experience of an individual who ingested the supplement, which experience is alleged by the individual, a family member of the individual, or a treating health professional to be associated with the supplement, whether or not such experience is considered to be related, casually or otherwise, to the supplement by a person referred to in paragraph (1) with respect to the supplement .

''(ii) The term 'serious', with respect to an adverse experience, means any of the following

outcomes: Death, a life-threatening condition, inpatient hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect.

''(B) The term 'documented incident', with respect to an ephedrine supplement, means a claim of a serious adverse experience that the applicable person under subsection (d)(1) has investigated to the extent of verifying that such an experience did occur, but without investigating the allegation that the experience is associated with the supplement.''.

(b) PROHIBITED ACT REGARDING REPORTING ON SERIOUS ADVERSE EXPERIENCES.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) The failure of a person to comply with any requirement under section 416(d).''.

(c) DEFINITIONS.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended by adding at the end the following:

''(nn)(1)(A) The term 'ephedrine group alkaloids', with respect to a dietary supplement, includes natural ephedrine group alkaloids and synthetic ephedrine group alkaloids.

''(B) The term 'natural ephedrine group alkaloids' means ephedrine group alkaloids present in or extracted from the herb ephedra or any other herb that contains ephedrine group alkaloids.

''(C) The term 'synthetic ephedrine group alkaloids' means ephedrine group alkaloids not present in or extracted from the herb ephedra or any other herb that contains ephedrine group alkaloids.

''(2)(A) The term 'new ephedrine group alkaloids' means ephedrine group alkaloids that are not generally recognized, among experts described in clause (B), as having been adequately shown through scientific procedures to present no significant or unreasonable risk of illness or injury under the conditions of use recommended or suggested in labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.

''(B) The experts referred to in clause (A) are experts qualified by scientific training and experience to evaluate whether ephedrine group alkaloids present no significant or unreasonable risk of illness or injury for purposes of such clause.''.

(d) EFFECTIVE DATES.—With respect to section 416 of the Federal Food, Drug, and Cosmetic Act (as added by this section):

(1) Subsection (a) of such section takes effect upon the expiration of 30 days after the date of the enactment of this Act. With respect to dietary supplements containing any ephedrine group alkaloids, shipments in commercial distribution as of the date of the enactment of this Act are subject to such subsection (a) to the extent determined appropriate by the Secretary of Health and Human Services.

(2) Subsection (d) of such section applies with respect to serious adverse experiences occurring on or after the date of the enactment of this Act, except to the extent that the person involved notifies the Secretary of Health and Human Services in writing that the person will not submit an application under subsection (a) of such section and will not be a packer or distributor of dietary supplements containing any ephedrine group alkaloids.

SEC. 3. PROVISIONS REGARDING ADULTERATED OR MISBRANDED SUPPLEMENTS.

(a) ADULTERATED SUPPLEMENTS.—

(1) DIETARY SUPPLEMENTS GENERALLY; REGULATIONS ON GOOD MANUFACTURING PRACTICE.—

(A) IN GENERAL.—Not later than 120 days after the date of the enactment of this Act, the Secretary of Health and Human Serv-

ices shall publish in the Federal Register a proposed rule for good manufacturing practice regulations under section 402(g) of the Federal Food, Drug, and Cosmetic Act.

(B) CONFORMING AMENDMENT.—Section 402(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2)) is amended in the first sentence by striking ''may'' and inserting ''shall'';

(2) EPHEDRINE GROUP ALKALOIDS.—Section 402(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(g)(2)) is amended—

(A) by striking ''(2)'' and inserting ''(2)(A)''; and

(B) by adding at the end the following:

''(B) In the case of dietary supplements containing ephedrine group alkaloids, regulations under clause (A) shall require the following:

''(i) The testing of each production lot or batch to ensure the accuracy of the label in stating the total amount of ephedrine group alkaloids contained in the supplement. Such tests shall be made using high performance liquid chromatography testing or other testing approved by the Secretary for purposes of this subclause.

''(ii) A determination of the expiration date of the supplements.

''(iii) The retention of reserve samples from each lot produced, stored under conditions consistent with the labeling of the supplements, until at least one year after the expiration date of the supplements.

''(iv) The implementation of distribution tracking procedures, including the use of lot numbers.''.

(b) MISBRANDED SUPPLEMENTS CONTAINING EPHEDRINE GROUP ALKALOIDS.—

(1) IN GENERAL.—Section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343) is amended by adding at the end the following:

''(w) If it is a dietary supplement containing any ephedrine group alkaloids, unless its label bears an expiration date.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) takes effect upon the effective date of the final rule for good manufacturing practice regulations under section 402(g) of the Federal Food, Drug, and Cosmetic Act.

○