

MICROBEAD-FREE WATERS ACT OF 2015

DECEMBER 7, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 1321]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 1321) to prohibit the sale or distribution of cosmetics containing synthetic plastic microbeads, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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The amendments areas follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Microbead-Free Waters Act of 2015”.

SEC. 2. PROHIBITION AGAINST SALE OR DISTRIBUTION OF RINSE-OFF COSMETICS CONTAINING PLASTIC MICROBEADS.

(a) **IN GENERAL.**—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

“(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

“(2) In this paragraph—

“(A) the term ‘plastic microbead’ means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

“(B) the term ‘rinse-off cosmetic’ includes toothpaste.”.

(b) **APPLICABILITY.**—

(1) **IN GENERAL.**—The amendment made by subsection (a) applies—

(A) with respect to manufacturing, beginning on July 1, 2017, and with respect to introduction or delivery for introduction into interstate commerce, beginning on July 1, 2018; and

(B) notwithstanding subparagraph (A), in the case of a rinse-off cosmetic that is a nonprescription drug, with respect to manufacturing, beginning on July 1, 2018, and with respect to the introduction or delivery for introduction into interstate commerce, beginning on July 1, 2019.

(2) **NONPRESCRIPTION DRUG.**—For purposes of this subsection, the term “nonprescription drug” means a drug not subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)).

(c) **PREEMPTION OF STATE LAWS.**—No State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect restrictions with respect to the manufacture or introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing plastic microbeads (as defined in section 301(ddd) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)) that are not identical to the restrictions under such section 301(ddd) that have begun to apply under subsection (b).

(d) **RULE OF CONSTRUCTION.**—Nothing in this Act (or the amendments made by this Act) shall be construed to apply with respect to drugs that are not also cosmetics (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)).

Amend the title so as to read: A bill to amend the Federal Food, Drug, and Cosmetic Act to prohibit the manufacture and introduction or delivery for introduction into interstate commerce of rinse-off cosmetics containing intentionally-added plastic microbeads.

PURPOSE AND SUMMARY

The purpose of H.R. 1321 is to ban plastic microbeads from rinse off cosmetic products to prevent them from getting into waterways across the United States. The legislation also will preempt State and local laws related to plastic microbeads in rinse off cosmetics. State and local governments have created a patchwork of differing laws, which creates problems for interstate commerce. Preemption will ensure certainty for manufacturers and other job creators across the country.

BACKGROUND AND NEED FOR LEGISLATION

Plastic Microbeads, commonly made of “polyethylene” or “polypropylene,” are synthetic plastic particles that are used as an abrasive in many personal-care products, such as face wash, body wash, soaps, shampoos, and toothpaste. Microbeads are too small to be filtered out by most sewer treatment facilities and make their way into our waterways and wildlife. Microbeads can absorb chemicals

commonly found in waterways and become large enough that they are mistaken for food by small fish and wildlife.

Many manufacturers are voluntarily phasing out the use of microbeads because of their environmental impact. To date, nine States have enacted microbeads legislation. An additional fifteen States are considering or have pending microbeads legislation.

H.R. 1321 would prohibit the manufacture, sale, or distribution of personal care products, including toothpaste, containing plastic microbeads beginning on July 1, 2017.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 1321 on May 1, 2015. The Subcommittee received testimony from:

- Dan Wyant, Director, Michigan Department of Environmental Quality;
- Linda R. Greenstein, Senator, New Jersey Legislature;
- Molly Flanagan, Alliance for the Great Lakes; and
- John Hurson, Executive Vice President of Government Relations, Personal Care Products Council.

COMMITTEE CONSIDERATION

On May 14, 2015, the Subcommittee on Health met in open markup session and forwarded H.R. 1321 to the full Committee, without amendment, by a voice vote. On November 17 and 18, 2015, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 1321 reported to the House, as amended, by a voice vote.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken in connection with ordering H.R. 1321 reported.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 1321 is to stop the use of plastic microbeads in rinse off cosmetics to prevent them from entering waterways.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 1321 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 1321 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, December 4, 2015.

Hon. FRED UPTON,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 1321, the Microbead-Free Waters Act of 2015.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Ellen Werble.

Sincerely,

KEITH HALL.

Enclosure.

H.R. 1321—Microbead-Free Waters Act of 2015

H.R. 1321 would amend the Federal Food, Drug, and Cosmetic Act to prohibit the manufacture, sale, or distribution of cosmetics containing plastic microbeads. CBO estimates that implementing H.R. 1321 would have no significant cost to the federal government. Enacting the bill would not affect direct spending or revenues; therefore, pay-as-you-go procedures do not apply. CBO estimates that enacting H.R. 1321 would not increase net direct spending or on-budget deficits in any of the four consecutive 10-year periods beginning in 2026.

The prohibition in the bill would impose an intergovernmental and private sector mandate as defined in the Unfunded Mandates Reform Act (UMRA). The mandate would affect distributors, sellers, and manufacturers of cosmetic products containing plastic microbeads. In addition, the bill would impose a separate intergovernmental mandate by preempting state laws.

CBO estimates that the cost of the mandate on distributors and sellers, including some public entities, would be minimal, if any, because the bill would provide those sellers with one year to sell any existing stock. Affected public entities would include a small number of pharmacies operating in public hospitals and some uni-

versity-affiliated retail stores. While the legislation also would preempt several states' laws, it would impose no duty on states that would result in additional spending or a loss of revenues. Taken together, CBO estimates that the aggregate costs, if any, of the intergovernmental mandates would fall well below the threshold established in UMRA for such mandates (\$77 million in 2015, adjusted annually for inflation).

Currently, many manufacturers of cosmetics have committed to removing microbeads from their products either on a voluntary basis or to comply with prohibitions enacted by states and localities. During the next few years, CBO expects that the incremental cost for those manufacturers to comply with the mandate in the bill would be minimal, if any. However, other manufacturers may need to reformulate their products or remove them from the market to comply with the mandate. Based on information from industry sources, CBO estimates that the cost of reformulating a cosmetic could total several million dollars and that the potential loss of income from removing a cosmetic from the market might be larger. Because the larger manufacturers of cosmetics have already announced plans to remove microbeads, CBO expects that only a small portion of the industry would need to take additional action to comply with the mandate. Further, some manufacturers also would experience savings because the bill would establish a uniform national standard that would preempt state and local laws, some of which are more stringent or have earlier deadlines than required under the bill. Consequently, CBO estimates that the net cost of the mandate would probably fall below the annual threshold established in UMRA for private-sector mandates (\$154 million, adjusted annually for inflation).

The CBO staff contacts for this estimate are Ellen Werble (for federal costs), J'nell Blanco Suchy (for intergovernmental mandates), and Amy Petz (for private-sector mandates). The estimate was approved by Holly Harvey, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 1321 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 1321 specifically directs to be completed no rule making within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

This section provides the short title of “Microbead-Free Waters Act of 2015”.

Section 2. Prohibition against sale or distribution of rinse-off cosmetics containing plastic microbeads

Subsection (a) would provide that the manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads is a prohibited act under section 301 of the Federal Food, Drug and Cosmetic Act (FFDCA). This section also defines the terms “plastic microbead” and “rinse-off cosmetic.”

Subsection (b) would establish effective dates for the prohibition in subsection (a). Additional time is provided for over-the-counter products that make cosmetic claims because of the Food and Drug Administration’s testing requirements for reformulations.

Subsection (c) would preempt State and local laws regarding the manufacture, introduction, or delivery of rinse-off cosmetics containing plastic microbeads into interstate commerce.

Subsection (d) would clarify that H.R. 1321 does not apply to drugs that are not also cosmetics, as defined in section 201 of the FFDCA.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in *italic* and existing law in which no change is proposed is shown in *roman*):

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404, 415, 505, or 564.

(e) The refusal to permit access to or copying of any record as required by section 412, 414, 417(j), 416, 504, 564, 703, 704(a), 760, or 761; or the failure to establish or maintain any record, or make any report, required under section 412, 414(b), 417, 416, 504, 505 (i) or (k), 512(a)(4)(C), 512 (j), (l) or (m), 572(i), 515(f), 519, 564, 760, 761, 909, or 920 or the refusal to permit access to or verification or copying of any such required record; or the violation of any recordkeeping requirement under section 204 of the FDA Food Safety Modernization Act (except when such violation is committed by a farm).

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, tobacco product, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404 or 721.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drugs a counterfeit drug.

(3) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 412, 414, 505, 510, 512, 513, 514, 515, 516, 518, 519, 520, 571, 572, 573, 704, 708, 721, 904, 905, 906, 907, 908, 909, or 920(b) concerning any method or process which as a trade secret is entitled to protection; or the violating of section 408(i)(2) or any regulation issued under that section.. This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee

or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b) or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

(o) In the case of a prescription drug distributed or offered for sale in interstate commerce, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable State law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved by the Secretary. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Act.

(p) The failure to register in accordance with section 510 or 905, the failure to provide any information required by section 510(j), 510(k), 905(i), or 905(j), or the failure to provide a notice required by section 510(j)(2) or 905(i)(3).

(q)(1) The failure or refusal—

(A) to comply with any requirement prescribed under section 518, 520(g), 903(b), 907, 908, or 915;

(B) to furnish any notification or other material or information required by or under section 519, 520(g), 904, 909, or 920; or

(C) to comply with a requirement under section 522 or 913.

(2) With respect to any device or tobacco product, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

(r) The movement of a device or tobacco product in violation of an order under section 304(g) or the removal or alteration of any mark or label required by the order to identify the device or tobacco product as detained.

(s) The failure to provide the notice required by section 412(c) or 412(e), the failure to make the reports required by section 412(f)(1)(B), the failure to retain the records required by section 412(b)(4), or the failure to meet the requirements prescribed under section 412(f)(3).

(t) The importation of a drug in violation of section 801(d)(1), the sale, purchase, or trade of a drug or drug sample or the offer to sell, purchase, or trade a drug or drug sample in violation of section 503(c), the sale, purchase, or trade of a coupon, the offer to sell, purchase, or trade such a coupon, or the counterfeiting of such a coupon in violation of section 503(c)(2), the distribution of a drug

sample in violation of section 503(d) or the failure to otherwise comply with the requirements of section 503(d), the distribution of drugs in violation of section 503(e), failure to comply with the requirements under section 582, the failure to comply with the requirements under section 584, as applicable, or the failure to otherwise comply with the requirements of section 503(e).

(u) The failure to comply with any requirements of the provisions of, or any regulations or orders of the Secretary, under section 512(a)(4)(A), 512(a)(4)(D), or 512(a)(5).

(v) The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 413.

(w) The making of a knowingly false statement in any statement, certificate of analysis, record, or report required or requested under section 801(d)(3); the failure to submit a certificate of analysis as required under such section; the failure to maintain records or to submit records or reports as required by such section; the release into interstate commerce of any article or portion thereof imported into the United States under such section or any finished product made from such article or portion, except for export in accordance with section 801(e) or 802, or with section 351(h) of the Public Health Service Act; or the failure to so export or to destroy such an article or portions thereof, or such a finished product.

(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.

(y) In the case of a drug, device, or food—

(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.

(z) The dissemination of information in violation of section 551.

(aa) The importation of a prescription drug in violation of section 804, the falsification of any record required to be maintained or provided to the Secretary under such section, or any other violation of regulations under such section.

(bb) The transfer of an article of food in violation of an order under section 304(h), or the removal or alteration of any mark or label required by the order to identify the article as detained.

(cc) The importing or offering for import into the United States of an article of food by, with the assistance of, or at the direction of, a person debarred under section 306(b)(3).

(dd) The failure to register in accordance with section 415.

(ee) The importing or offering for import into the United States of an article of food in violation of the requirements under section 801(m).

(ff) The importing or offering for import into the United States of a drug or device with respect to which there is a failure to com-

ply with a request of the Secretary to submit to the Secretary a statement under section 801(o).

(gg) The knowing failure to comply with paragraph (7)(E) of section 704(g); the knowing inclusion by a person accredited under paragraph (2) of such section of false information in an inspection report under paragraph (7)(A) of such section; or the knowing failure of such a person to include material facts in such a report.

(hh) The failure by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food to comply with the sanitary transportation practices prescribed by the Secretary under section 416.

(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.

(jj)(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).

(kk) The dissemination of a television advertisement without complying with section 503B.

(ll) The introduction or delivery for introduction into interstate commerce of any food to which has been added a drug approved under section 505, a biological product licensed under section 351 of the Public Health Service Act, or a drug or a biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, unless—

(1) such drug or such biological product was marketed in food before any approval of the drug under section 505, before licensure of the biological product under such section 351, and before any substantial clinical investigations involving the drug or the biological product have been instituted;

(2) the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, approving the use of such drug or such biological product in the food;

(3) the use of the drug or the biological product in the food is to enhance the safety of the food to which the drug or the biological product is added or applied and not to have independent biological or therapeutic effects on humans, and the use is in conformity with—

(A) a regulation issued under section 409 prescribing conditions of safe use in food;

(B) a regulation listing or affirming conditions under which the use of the drug or the biological product in food is generally recognized as safe;

(C) the conditions of use identified in a notification to the Secretary of a claim of exemption from the premarket approval requirements for food additives based on the notifier's determination that the use of the drug or the biological

cal product in food is generally recognized as safe, provided that the Secretary has not questioned the general recognition of safety determination in a letter to the notifier;

(D) a food contact substance notification that is effective under section 409(h); or

(E) such drug or biological product had been marketed for smoking cessation prior to the date of the enactment of the Food and Drug Administration Amendments Act of 2007; or

(4) the drug is a new animal drug whose use is not unsafe under section 512.

(mm) The failure to submit a report or provide a notification required under section 417(d).

(nn) The falsification of a report or notification required under section 417(d).

(oo) The sale of tobacco products in violation of a no-tobacco-sale order issued under section 303(f).

(pp) The introduction or delivery for introduction into interstate commerce of a tobacco product in violation of section 911.

(qq)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp (including tax stamp), tag, label, or other identification device upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other item that is designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any tobacco product or container or labeling thereof so as to render such tobacco product a counterfeit tobacco product.

(3) The doing of any act that causes a tobacco product to be a counterfeit tobacco product, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit tobacco product.

(rr) The charitable distribution of tobacco products.

(ss) The failure of a manufacturer or distributor to notify the Attorney General and the Secretary of the Treasury of their knowledge of tobacco products used in illicit trade.

(tt) Making any express or implied statement or representation directed to consumers with respect to a tobacco product, in a label or labeling or through the media or advertising, that either conveys, or misleads or would mislead consumers into believing, that—

(1) the product is approved by the Food and Drug Administration;

(2) the Food and Drug Administration deems the product to be safe for use by consumers;

(3) the product is endorsed by the Food and Drug Administration for use by consumers; or

(4) the product is safe or less harmful by virtue of—

(A) its regulation or inspection by the Food and Drug Administration; or

(B) its compliance with regulatory requirements set by the Food and Drug Administration;

including any such statement or representation rendering the product misbranded under section 903.

(uu) The operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418.

(vv) The failure to comply with the requirements under section 419.

(ww) The failure to comply with section 420.

(xx) The refusal or failure to follow an order under section 423.

(yy) The knowing and willful failure to comply with the notification requirement under section 417(h).

(zz) The importation or offering for importation of a food if the importer (as defined in section 805) does not have in place a foreign supplier verification program in compliance with such section 805.

(aaa) The failure to register in accordance with section 801(s).

(bbb) The failure to notify the Secretary in violation of section 568.

(ccc)(1) The resale of a compounded drug that is labeled “not for resale” in accordance with section 503B.

(2) With respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable.

(3) The failure to report drugs or adverse events by an entity that is registered in accordance with subsection (b) of section 503B.

(ddd)(1) The manufacture or the introduction or delivery for introduction into interstate commerce of a rinse-off cosmetic that contains intentionally-added plastic microbeads.

(2) In this paragraph—

(A) the term “plastic microbead” means any solid plastic particle that is less than five millimeters in size and is intended to be used to exfoliate or cleanse the human body or any part thereof; and

(B) the term “rinse-off cosmetic” includes toothpaste.

* * * * *