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113TH CONGRESS
2D SESSION

H. R. 5350

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to allow the marketing, distribution, or sale of solid antimicrobial copper alloys with certain claims, to amend the Federal Food, Drug, and Cosmetic Act to exclude certain solid antimicrobial copper alloys from regulation as drugs or devices, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 31, 2014

Mr. LATTA (for himself and Mr. MURPHY of Pennsylvania) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Agriculture, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to allow the marketing, distribution, or sale of solid antimicrobial copper alloys with certain claims, to amend the Federal Food, Drug, and Cosmetic Act to exclude certain solid antimicrobial copper alloys from regulation as drugs or devices, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Infection Reduction Labeling Act of 2014''.

SEC. 2. TREATMENT OF SOLID ANTIMICROBIAL COPPER ALLOYS UNDER FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT.

Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a) is amended by adding at the end the following new subsection:

''(i) CLAIMS MADE FOR SOLID ANTIMICROBIAL COPPER ALLOYS.—

''(1) CERTAIN CLAIMS AUTHORIZED.—Notwithstanding any other provision of this Act, solid antimicrobial copper alloys, and products made from such alloys, may be marketed, distributed, or sold with labeling making claims regarding the microbial reduction or infection control efficacy of the alloys if the claims are consistent with the results of—

''(A) federally-funded clinical trials finding greater than 25 percent reductions in infection rate or 50 percent reductions in microbial burden; or

''(B) federally-funded clinical trials finding statistically significant reductions in infection rate or microbial burden.

"(2) SUBMISSION OR REVIEW OF EFFICACY DATA WAIVED.—The registration of solid antimicrobial copper alloys under this section shall not require submission or review of efficacy data related to claims consistent with the results of the clinical trials described in paragraph (1).

"(3) CONSISTENCY OF CLAIMS WITH AGENCY-REGISTERED PRODUCT LABEL.—

"(A) IN GENERAL.—Claims described in paragraph (1) shall be consistent with the product label registered under this section.

"(B) PROCESS FOR MODIFICATION OF LABELING.—In lieu of the notification process under subsection (c)(9), registration of a solid antimicrobial copper alloy may be modified to ensure the consistency of claims described in paragraph (1) with the product labeling pursuant to the following process:

"(i) The registrant shall submit a notification identifying the proposed claims that are consistent with the results of the clinical trials described in paragraph (1), and include a copy of the proposed amended product label.

"(ii) Within 30 days after receipt of such a notification, the Administrator shall—

"(I) notify the registrant in writing if the Administrator objects to any of the proposed claims as not consistent with the results of the clinical trials described in paragraph (1); and

"(II) state the reasons why.

"(iii) A registrant may file a response to any such objection not later than 30 days after the registrant's receipt of the objection.

"(iv) After receipt and consideration of any such response, the Administrator shall issue a decision within 30 days.

"(v) A decision under clause (iv) shall be considered to be a final agency action.

"(vi) A registrant may distribute or sell a solid antimicrobial copper alloy product with the claims described in paragraph (1) after 60 days of submission of the notification described in this subparagraph, unless the Administrator issues an objection as described in this subparagraph.

"(4) DEFINITION.—In this subsection, the term 'solid antimicrobial copper alloy' means a solid copper alloy that—

"(A) is registered under this section;

"(B) is listed under Environmental Protection Agency registration number 82012–1, 82012–2, 82012–3, 82012–4, 82012–5, or 82012–6, or is otherwise identified by a Unified Numbering System code in an Environmental Protection Agency registration;

"(C) has a copper content of not less than 60 weight percent; and

"(D) has a content of not more than 0.1 weight percent of each of the following: lead, chromium, and arsenic.".

SEC. 3. TREATMENT OF SOLID ANTIMICROBIAL COPPER ALLOYS UNDER FEDERAL FOOD, DRUG, AND COSMETIC ACT.

Subchapter E of chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 569C of such Act (21 U.S.C. 360bbb–8c) the following:

"SEC. 569D. SOLID ANTIMICROBIAL COPPER ALLOYS.

"(a) EXCLUSION FROM TREATMENT AS DRUG OR DEVICE.—A product that is made from solid antimicrobial

copper alloy and has labeling making a claim regarding the microbial reduction or infection control efficacy of the alloy, consistent with the results of federally-funded clinical trials, shall not, by virtue of such claim—

"(1) be treated as a drug or device, or as a combination thereof, for purposes of this Act; or

"(2) otherwise be subject to regulation by the Food and Drug Administration.

"(b) DEFINITION.—In this section, the term 'solid antimicrobial copper alloy' means a solid copper alloy that—

"(1) is listed under Environmental Protection Agency registration number 82012–1, 82012–2, 82012–3, 82012–4, 82012–5, or 82012–6, or is otherwise identified by a Unified Numbering System code in an Environmental Protection Agency registration;

"(2) has a copper content of not less than 60 weight percent; and

"(3) has a content of not more than 0.1 weight percent of each of the following: lead, chromium, and arsenic.".

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