

113TH CONGRESS
2^D 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

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Infection Reduction
3 Labeling Act of 2014”.

4 **SEC. 2. TREATMENT OF SOLID ANTIMICROBIAL COPPER AL-**
5 **LOYS UNDER FEDERAL INSECTICIDE, FUN-**
6 **GICIDE, AND RODENTICIDE ACT.**

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

10 “(i) **CLAIMS MADE FOR SOLID ANTIMICROBIAL COP-**
11 **PER ALLOYS.—**

12 “(1) **CERTAIN CLAIMS AUTHORIZED.—**Notwith-
13 standing any other provision of this Act, solid anti-
14 microbial copper alloys, and products made from
15 such alloys, may be marketed, distributed, or sold
16 with labeling making claims regarding the microbial
17 reduction or infection control efficacy of the alloys if
18 the claims are consistent with the results of—

19 “(A) federally-funded clinical trials finding
20 greater than 25 percent reductions in infection
21 rate or 50 percent reductions in microbial bur-
22 den; or

23 “(B) federally-funded clinical trials finding
24 statistically significant reductions in infection
25 rate or microbial burden.

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

7 “(3) CONSISTENCY OF CLAIMS WITH AGENCY-
8 REGISTERED PRODUCT LABEL.—

9 “(A) IN GENERAL.—Claims described in
10 paragraph (1) shall be consistent with the prod-
11 uct label registered under this section.

12 “(B) PROCESS FOR MODIFICATION OF LA-
13 BELING.—In lieu of the notification process
14 under subsection (c)(9), registration of a solid
15 antimicrobial copper alloy may be modified to
16 ensure the consistency of claims described in
17 paragraph (1) with the product labeling pursu-
18 ant to the following process:

19 “(i) The registrant shall submit a no-
20 tification identifying the proposed claims
21 that are consistent with the results of the
22 clinical trials described in paragraph (1),
23 and include a copy of the proposed amend-
24 ed product label.

1 “(ii) Within 30 days after receipt of
2 such a notification, the Administrator
3 shall—

4 “(I) notify the registrant in writ-
5 ing if the Administrator objects to any
6 of the proposed claims as not con-
7 sistent with the results of the clinical
8 trials described in paragraph (1); and

9 “(II) state the reasons why.

10 “(iii) A registrant may file a response
11 to any such objection not later than 30
12 days after the registrant’s receipt of the
13 objection.

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

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

19 “(vi) A registrant may distribute or
20 sell a solid antimicrobial copper alloy prod-
21 uct with the claims described in paragraph
22 (1) after 60 days of submission of the noti-
23 fication described in this subparagraph,
24 unless the Administrator issues an objec-
25 tion as described in this subparagraph.

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

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

7 “(2) otherwise be subject to regulation by the
8 Food and Drug Administration.

9 “(b) DEFINITION.—In this section, the term ‘solid
10 antimicrobial copper alloy’ means a solid copper alloy
11 that—

12 “(1) is listed under Environmental Protection
13 Agency registration number 82012–1, 82012–2,
14 82012–3, 82012–4, 82012–5, or 82012–6, or is oth-
15 erwise identified by a Unified Numbering System
16 code in an Environmental Protection Agency reg-
17 istration;

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

20 “(3) has a content of not more than 0.1 weight
21 percent of each of the following: lead, chromium,
22 and arsenic.”.

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