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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R.

To amend the Federal Food, Drug, and Cosmetic Act to ensure public participation in the drafting and issuance of Level 1 guidance documents, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. GUTHRIE (for himself, Mr. SHIMKUS, and Mr. ROGERS of Michigan) introduced the following bill; which was referred to the Committee on

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to ensure public participation in the drafting and issuance of Level 1 guidance documents, 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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Guidance Account-
5 ability and Transparency Act of 2011”.

1 **SEC. 2. PUBLIC PARTICIPATION IN ISSUANCE OF FDA GUID-**
2 **ANCE DOCUMENTS.**

3 Subparagraph (C) of section 701(h)(1) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)) is
5 amended to read as follows:

6 “(C) For any guidance document that sets
7 forth initial interpretations of a statute or regu-
8 lation, sets forth changes in interpretation or
9 policy that are of more than a minor nature, in-
10 cludes complex scientific issues, or covers highly
11 controversial issues—

12 “(i) the Secretary shall—

13 “(I) at least 3 months before
14 issuance of a draft, publish notice in
15 the Federal Register of the Sec-
16 retary’s intent to prepare such a guid-
17 ance document; and

18 “(II) during preparation and be-
19 fore issuance of a draft, meet with in-
20 terested stakeholders and solicit public
21 comment;

22 “(ii) if the Secretary for good cause
23 finds that compliance with clause (i) is im-
24 practicable, unnecessary, or contrary to the
25 public interest—

1 “(I) the Secretary shall publish
2 such finding and a brief statement of
3 the reasons therefor in the Federal
4 Register;

5 “(II) clause (i) shall not apply;
6 and

7 “(III) during a period of at least
8 3 months beginning not later than the
9 date of issuance of a draft, the Sec-
10 retary shall meet with interested
11 stakeholders and solicit public com-
12 ment;

13 “(iii) upon issuance of a draft under
14 clause (i) or (ii), the Secretary shall—

15 “(I) designate the draft as pro-
16 posed or final; and

17 “(II) not later than 12 months
18 after the date of issuance of a pro-
19 posed draft, issue a final draft in ac-
20 cordance with clauses (i) and (ii);

21 “(iv) if the Secretary issues a pro-
22 posed draft and fails to finalize the draft
23 by the deadline determined under clause
24 (iii)(II), the Secretary shall, beginning on

1 the date of such deadline, treat the pro-
2 posed draft as null and void; and

3 “(v) not less than every 5 years after
4 the issuance of a final guidance document
5 in accordance with clause (iii), the Sec-
6 retary shall—

7 “(I) conduct a retrospective anal-
8 ysis of such guidance document to en-
9 sure it is not outmoded, ineffective,
10 insufficient, or excessively burden-
11 some; and

12 “(II) based on such analysis,
13 modify, streamline, expand, or repeal
14 the guidance document in accordance
15 with what has been learned.

16 “(D) A notice to industry guidance letter,
17 a notice to industry advisory letter, and any
18 similar notice that sets forth initial interpreta-
19 tions of a statute or regulation, sets forth
20 changes in interpretation or policy that are of
21 more than a minor nature, includes complex sci-
22 entific issues, or covers highly controversial
23 issues shall be treated as a guidance document
24 for purposes of subparagraph (C).”.