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112TH CONGRESS
1ST SESSION

H. R. 3204

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

OCTOBER 14, 2011

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

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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.

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 ''Guidance Accountability and Transparency Act of 2011''.

SEC. 2. PUBLIC PARTICIPATION IN ISSUANCE OF FDA GUIDANCE DOCUMENTS.

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

''(C) For any guidance document that sets forth initial interpretations of a statute or regulation, sets forth changes in interpretation or policy that are of more than a minor nature, includes complex scientific issues, or covers highly controversial issues—

''(i) the Secretary shall—

''(I) at least 3 months before issuance of a draft, publish notice in the Federal Register of the Secretary's intent to prepare such a guidance document; and

''(II) during preparation and before issuance of a draft, meet with interested stakeholders and solicit public comment;

''(ii) if the Secretary for good cause finds that compliance with clause (i) is impracticable, unnecessary, or contrary to the public interest—

''(I) the Secretary shall publish such finding and a brief statement of the reasons therefor in the Federal Register;

''(II) clause (i) shall not apply; and

''(III) during a period of at least 3 months beginning not later than the date of issuance of a draft, the Secretary shall meet with interested stakeholders and solicit public comment;

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

''(I) designate the draft as proposed or final; and

''(II) not later than 12 months after the date of issuance of a proposed draft, issue a final draft in accordance with clauses (i) and (ii);

''(iv) if the Secretary issues a proposed draft and fails to finalize the draft by the deadline determined under clause (iii)(II), the Secretary shall, beginning on

the date of such deadline, treat the proposed draft as null and void; and

''(v) not less than every 5 years after the issuance of a final guidance document in accordance with clause (iii), the Secretary shall—

''(I) conduct a retrospective analysis of such guidance document to ensure it is not outmoded, ineffective, insufficient, or excessively burdensome; and

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

''(D) A notice to industry guidance letter, a notice to industry advisory letter, and any similar notice that sets forth initial interpretations of a statute or regulation, sets forth changes in interpretation or policy that are of more than a minor nature, includes complex scientific issues, or covers highly controversial issues shall be treated as a guidance document for purposes of subparagraph (C).''.

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