APPENDIX A

***Title 21 Food and Drugs***

***§ 202.1 Prescription-drug advertisements.***

(e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:

(5) *"True statement" of information.* An advertisement does not satisfy the requirement that it present a "true statement" of information in brief summary relating to side effects, contraindications, and effectiveness if:

(i) It is false or misleading with respect to side effects, contraindications, or effectiveness; or

**(ii) It fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug in that the information relating to effectiveness is presented in greater scope, depth, or detail than is required by section 502(n) of the act and this information is not fairly balanced by a presentation of a summary of true information relating to side effects and contraindications of the drug; *Provided, however,* That no advertisement shall be considered to be in violation of this section if the presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness or safety.**

(iii) It fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as recommended or suggested in the advertisement.

Appendix B



The information collection provisions in §§ 314.70, 601.12, 807.81, and 814.39 have been approved under OMB control numbers 0910–0001, 0910–0338, 0910–0120, and 0910–0231, respectively.

Dated: April 22, 2011.

Leslie Kux,

*Acting Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2011–N–0230]

### Agency Information Collection Activities; Proposed Collection; Comment Request; Examination of Online Direct-to-Consumer Prescription Drug Promotion

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on a series of studies, Examination of Online Direct-to-Consumer Prescription Drug Promotion. These studies are designed to test different ways of presenting benefit and risk information in online direct-to-consumer (DTC) prescription drug Web sites.

**DATES:** Submit either electronic or written comments on the collection of information by June 27, 2011.

**ADDRESSES:** Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, e-mail: *Ila.Mizrachi@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

### Examination of Online Direct-to-Consumer Prescription Drug Promotion—(OMB Control Number 0910—New)

Pharmaceutical products are launched and marketed in a number of new modalities and venues that did not exist a short time ago. Increasingly, prescription products are promoted to consumers online in such formats as banner ads, Web sites, and videos. The interactive nature of the Internet allows for features not possible with traditional media (*i.e.*, print, radio, and television), such as scrolling information, pop up windows, linking to more information, and embedding videos. FDA regulations require that prescription drug advertisements include a "fair balance" of information about the benefits and risks of advertised products, both in terms of the content and presentation of the information (21 CFR 202.1(e)(5)(ii)). All prescription drug ads that make claims about a product must, therefore, also include risk information in a "balanced" manner. Currently, there are a number of questions surrounding how to achieve "fair balance" in online DTC promotion.

A few studies have examined how well online DTC Web sites communicate benefit and risk information. Although content analyses demonstrate that most Web sites include information on side effects and contraindications (Ref. 1), risk information is often presented less prominently and in fewer locations on the Web site (Refs. 2, 3, and 4). Content analyses also suggest that risk information on DTC prescription drug Web sites is often incomplete (Ref. 5) and written at very high literacy levels (Ref. 6).

One study examined how users interact with prescription drug Web sites (Ref. 7). This study found that the placement of risk and benefit information on a Web site is an important factor in whether it achieves "fair balance." Specifically, participants' ability to find and accurately recall risk information was enhanced when risk and benefit information were presented separately and when risk information was presented on a higher order page (*i.e.*, on a second-level page clearly linked from the homepage or on the homepage).

This project is designed to test different ways of presenting prescription drug risk and benefit information on branded drug Web sites. This research is relevant to current policy questions and debate and will complement qualitative research we plan to conduct on issues surrounding social media. The original regulations that presently determine FDA's position on DTC promotion were written at a time when the available media for DTC promotion were print and broadcast, and the primary audience was health care professionals. This dynamic is shifting, and evidence is needed to support guidance development. The series of studies described in this notice will provide data that, along with other input and considerations, will inform the development of future guidance.

*Design Overview:* This research will be conducted in three concurrent studies. The first three studies are experimental and the fourth is qualitative.

The purpose of study 1 is to investigate whether the presentation of risk information on branded drug Web sites influences consumers' perceptions and understanding of the risks and benefits of the product. In study 1, we will examine the format (*e.g.*, whether the risk information is presented in a paragraph or as a bulleted list) and