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.

[FR Doc. 2011–10254 Filed 4–27–11; 8:45 am]

BILLING CODE 4160–01–P

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

visibility (*i.e.,* the risk information can be seen without scrolling down versus the risk information cannot be seen without scrolling down) of risk information on the homepage of a prescription drug Web site. Participants will be randomly assigned to experimental conditions in a factorial design as follows:

TABLE 1—STUDY 1 PROPOSED DESIGN (2×5)

Visibility	Format				
	Paragraph	Bullet list	Checklist	Highlighted box	Animated spokesperson
Scrolling Needed					
No Scrolling Needed					

The purpose of study 2 is to investigate how special features such as personal testimonial videos and interactive visuals on branded drug Web sites influence perceptions and understanding of the risks and benefits of the product. Examples of special features we may examine include personal testimonial video and interactive mechanism of action visuals. We will examine these special features in the context of the prominence of the presentation of risk information in two levels, more prominent and less prominent. An example of a more prominent display of risk information might involve including the risks as part of the spoken testimonial, whereas a less prominent display may involve a scrolling text of the risks after the animated video. We will include a control condition in which participants view a Web page with no special features. Participants will be randomly assigned to experimental conditions in a factorial design as follows:

TABLE 2—STUDY 2 PROPOSED DESIGN (2×2+1)

Risk presentation	Special features		
	Personal testimonial	Interactive visual	Control group
Prominent			
Less Prominent			

The purpose of study 3 is to investigate whether links to and citations from external organizations referenced on the homepage of branded drug Web sites influence consumer perceptions and understanding of the risks and benefits of the product. We will examine two types of information: Hyperlinks to the external organization's Web site (*e.g.,* a link to the American Heart Association) and citations from an external organization (*e.g.,* a citation to American Heart Association guidelines). We will also examine the type of organization (*e.g.,* nonprofit or online health community). Participants will be randomly assigned to experimental conditions in a factorial design as follows:

TABLE 3—STUDY 3 PROPOSED DESIGN (8×2+1)

Organization type	Information type	
	Hyperlink to organization Web site	Citation
Government		
Nonprofit		
Health Care		
Health Professions Associations		
Academic		
Commercial		
Online Health Community		
Pharmaceutical Company-Sponsored Community		
Control Group		

In these three studies, participants will be randomly assigned to view one version of a (fictitious) prescription drug Web site. After viewing the Web site, participants will answer a series of questions about the drug. We will test how the manipulations affect outcomes such as perceived efficacy, perceived risk, behavioral intention, and accurate understanding of the benefit and risk information. In each study, the fictitious prescription drug will be for the treatment of a high prevalence medical condition and modeled on an actual drug used to treat that condition. Participants will be consumers who have been diagnosed with the medical condition of interest. For instance, the medical conditions may be high cholesterol and seasonal allergies for study 1, depression and acid reflux disease for study 2, and high blood pressure for study 3.

For studies 1 to 3, interviews are expected to last no more than 25 minutes (the questionnaire is available upon request). This will be a one-time (rather than annual) collection of information.

FDA estimates the burden of this collection of information as follows:

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours) [2]	Total hours
Screener	20,000	1	20,000	2/60	667
Pretests	1,200	1	1,200	20/60	400
Study 1	4,000	1	4,000	25/60	1,667
Study 2	2,000	1	2,000	25/60	834
Study 3	3,600	1	3,600	25/60	1,500
Total					5,068

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

I. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Macias, W. and L. Stavchansky Lewis, "How Well Do Direct-to-Consumer (DTC) Prescription Drug Web Sites Meet FDA Guidelines and Public Policy Concerns?" *Health Marketing Quarterly,* vol. 22, pp. 45–71, 2005.
2. Hicks, K. E., M. S. Wogalter, and W. J. Vigilante, Jr., "Placement of Benefits and Risks in Prescription Drug Manufacturers' Web Sites and Information Source Expectations," *Drug Information Journal,* vol. 39, pp. 267–278, 2005.
3. Huh, J. and B. J. Cude, "Is the Information 'Fair and Balanced' in Direct-to-Consumer Prescription Drug Web Sites?" *Journal of Health Communication,* vol. 9, pp. 529–540, 2004.
4. Sheehan, K. B., "Direct-to-Consumer (DTC) Branded Drug Web Sites Risk Presentation and Implications for Public Policy," *Journal of Advertising,* vol. 36, pp. 123–135, 2007.
5. Davis, J. J., E. Cross, and J. Crowley, "Pharmaceutical Web Sites and the Communication of Risk Information," *Journal of Health Communication,* vol. 12, pp. 29–39, 2007.
6. Naik, S. and S. P. Desselle, "An Evaluation of Cues, Inducements, and Readability of Information on Drug-Specific Web Sites," *Journal of Pharmaceutical Marketing and Management,* vol. 17, pp. 61–81, 2007.
7. Vigilante, Jr., W. J., and M. S. Wogalter, "Assessing Risk and Benefit Communication in Direct-to-Consumer Medication Web Site Advertising," *Drug Information Journal,* vol. 39, pp. 3–12, 2005.

Dated: April 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–10253 Filed 4–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0287]

Guidance for Industry on Fish and Fishery Products Hazards and Controls, Fourth Edition; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition." The updated guidance supports and complements FDA's regulations for the safe and sanitary processing and importing of fish and fishery products using hazard analysis and critical control point (HACCP) methods.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Contact the Florida Sea Grant, IFAS–Extension Bookstore, University of Florida, P.O. Box 110011, Gainesville, FL 32611–0011, 1–800–226–1764, for single copies of this guidance. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Bruce F. Wilson, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of the guidance for industry entitled "Fish and Fishery Products Hazards and Controls Guidance, Fourth Edition." This guidance is being issued consistent with FDA's good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). This guidance is being implemented without prior public comment because the Agency has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). The Agency made this determination because the updated information in this guidance will significantly enhance the seafood industry's ability to protect the public health and will provide important recommendations for conducting a hazard analysis and implementing a HACCP plan. Although this guidance document is immediately in effect, it remains subject to comment in accordance with the Agency's GGP regulation.

This guidance provides industry with information that will assist processors of seafood products in identifying the likelihood that a food safety hazard may occur in their product and will guide them in the preparation of appropriate HACCP plans for those hazards that are reasonably likely to occur. A summary of the changes from the third edition is included in the discussion section of the guidance.

Under FDA's fish and fishery products regulations (part 123 (21 CFR part 123)), processors of fish and fishery products are required to operate preventive control systems under the principles of HACCP. Fish and fishery products are adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(4)) if a processor fails to have and implement a HACCP plan when one is necessary