Dated: April 21, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–10256 Filed 4–27–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Prospective Granting of an Exclusive License

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This is a notice in accordance with 35 U.S.C. 209(e) and 37 CFR 404.7(a)(1)(i) that the Technology Transfer Office of the Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS), is contemplating granting a worldwide exclusive license to AES Raptor, LLC, located in North Kansas City, Missouri. Under this exclusive license, only AES Raptor, LLC would be permitted to commercialize the technology described in the patent applications listed below. CDC intends to grant rights to commercialize this invention to no other licensees. The patent rights in this invention have been assigned to the government of the United States of America. The invention to be licensed is:

Title: Barricade System and Barricade Bracket for Use Therein, CDC Ref. #: I–016–04, a safety rail system that provides protection to individuals working on inclined structures. The system is designed to prevent individuals from falls to a lower level.

U.S. Patent No.: 7,509,702.

U.S. Application No.: 11/257,472.

Filing date: 10/24/2005.

Canadian Application No.: 2,565,354.

Filing date: October 23, 2006.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7.

ADDRESSES: Requests for a copy of this patent application, inquiries, comments, and other materials relating to the contemplated licenses should be directed to Andrew Watkins, Director, Technology Transfer Office, Centers for Disease Control and Prevention (CDC), 4770 Buford Highway, Mailstop K–79, Atlanta, GA 30341, telephone: (770) 488–8610; facsimile: (770) 488–8615. Applications for an exclusive license filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Only written comments and/or applications for a license which are received by CDC within thirty days of this notice will be considered. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Tanja Popovic,

Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2011–10257 Filed 4–27–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0588]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by May 31, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0614. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile; Interim Final Rule—(OMB Control Number 0910–0614)—Extension

Under the Public Health Service Act (PHS Act), the Department of Health and Human Services stockpiles medical products that are essential to the health security of the nation (see PHS Act, section 319F–2, 42 U.S.C. 247d–6b). This collection of medical products for use during national health emergencies, known as the Strategic National Stockpile (SNS), is to "provide for the emergency health security of the United States, including the emergency health security of children and other vulnerable populations, in the event of a bioterrorist attack or other public health emergency."

It may be appropriate for certain medical products that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling regulations given their anticipated circumstances of use in an emergency. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the FD& C Act) (21 U.S.C. 352).

In the **Federal Register** of December 28, 2007 (72 FR 73589), FDA published an interim final rule entitled "Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile." In the interim final rule, FDA issued regulations under §§ 201.26, 610.68, 801.128, and 809.11 (21 CFR 201.26, 610.68, 801.128, and 809.11), which allow the appropriate FDA Center Director to grant a request for an exception or alternative to certain regulatory provisions pertaining to the labeling of human drugs, biological products, medical devices, and in vitro diagnostics that currently are or will be included in the SNS if certain criteria are met. The appropriate FDA Center Director may grant an exception or alternative to certain FDA labeling requirements if compliance with these labeling requirements could adversely affect the safety, effectiveness, or availability of products that are or will be included in the SNS. An exception or alternative granted under the

regulations may include conditions or safeguards so that the labeling for such products includes appropriate information necessary for the safe and effective use of the product given the product's anticipated circumstances of use. Any grant of an exception or alternative will only apply to the specified lots, batches, or other units of medical products in the request. The appropriate FDA Center Director may also grant an exception or alternative to the labeling provisions specified in the regulations on his or her own initiative.

Under §§ 201.26(b)(1)(i) (human drug products), 610.68(b)(1)(i) (biological products), 801.128(b)(1)(i) (medical devices), and 809.11(b)(1)(i) (in vitro diagnostic products for human use), an SNS official or any entity that manufactures (including labeling, packing, relabeling, or repackaging), distributes, or stores such products that are or will be included in the SNS may submit, with written concurrence from a SNS official, a written request for an exception or alternative to certain labeling requirements to the appropriate FDA Center Director. Except when initiated by an FDA Center Director, a request for an exception or alternative must be in writing and must:

- Identify the specified lots, batches, or other units of the affected product;
- Identify the specific labeling provisions under this rule that are the subject of the request;
- Explain why compliance with the specified labeling provisions could adversely affect the safety, effectiveness, or availability of the product subject to the request;
- Describe any proposed safeguards or conditions that will be implemented so that the labeling of the product includes appropriate information necessary for the safe and effective use of the product given the anticipated circumstances of use of the product;
- Provide copies of the proposed labeling of the specified lots, batches, or other units of the affected product that will be subject to the exception or alternative; and
- Provide any other information requested by the FDA Center Director in support of the request.

If the request is granted, the manufacturer may need to report to FDA any resulting changes to the New Drug Application, Biologics License Application, Premarket Approval Application, or Premarket Notification (510(k)) in effect, if any. The submission and grant of an exception or an alternative to the labeling requirements specified in the interim final may be used to satisfy certain reporting obligations relating to changes to product applications under § 314.70 (21 CFR 314.70) (human drugs), § 601.12 (21 CFR 601.12) (biological products), § 814.39 (21 CFR 814.39) (medical devices subject to premarket approval), or § 807.81 (21 CFR 807.81) (medical devices subject to 510(k) clearance requirements). 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. On a case-by-case basis, the appropriate FDA Center Director may also determine when an exception or alternative is granted that certain safeguards and conditions are appropriate, such as additional labeling on the SNS products, so that the labeling of such products would include information needed for safe and effective use under the anticipated circumstances of use.

Respondents to this collection of information are entities that manufacture (including labeling, packing, relabeling, or repackaging), distribute, or store affected SNS products. Based on the number of requests for an exception or alternative received by FDA since issuance of the interim final rule, FDA estimates an average of two requests annually. FDA is estimating that each respondent will spend an average of 24 hours preparing each request. The hours per response for each submission are based on the estimated time that it takes to prepare a supplement to an application, which may be considered similar to a request for an exception or alternative. To the extent that labeling changes not already required by FDA regulations are made in connection with an exception or alternative granted under the interim rule, FDA is estimating one occurrence annually in the event FDA would require any additional labeling changes not already covered by FDA regulations, and that it would take 8 hours to develop and revise the labeling to make such changes.

In the **Federal Register** of November 30, 2010 (75 FR 74062), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.119(b)(1)(i)	2	1	2	24	48
201.26(b)(1)(i), 610.68(b)(1)(i), 801.128(b)(1)(i), and 809.11(b)(1)(i) ..	1	1	1	8	8
Total					56

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

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