necessary to address any potential questions regarding the safety, labeling, or regulatory status of the food or food ingredient. As such, these consultations have provided assistance to both industry and the Agency in exercising their mutual responsibilities under the FD&C Act.

Generally, for an initial consultation, a developer requests a meeting by sending FDA a letter with an agenda. A mutually convenient time is arranged and the developer comes to discuss their product. In preparation for a meeting, a developer might prepare written materials or a slide presentation to discuss their product under development. A meeting between the developer and FDA typically lasts between 1 and 2 hours. As a result of such a meeting, FDA establishes a file called a biotechnology notification file, or BNF, to collect all documentation and communication regarding the bioengineered plant. For example, FDA typically places information such as the developer's letter, agenda, and any written materials (such as copies of a slide presentation) in a BNF, as well as any memorandum FDA prepares as a record of the meeting. FDA has not issued any recommendations as to the format for these types of materials (*e.g.,* there is no form associated with requesting a meeting).

Depending on the introduced trait, the experience the developer has had with the kind of modification being considered, and their familiarity with the consultation procedures, a developer might choose to do a final consultation without an initial consultation.

III. Final Consultations

Final consultations are a one-time burden. At some stage in the process of research and development, a developer will have accumulated the information that the developer believes is adequate to ensure that food derived from the new plant variety is safe and that it demonstrates compliance with the relevant provisions of the FD&C Act. The developer will then be in a position to conclude any ongoing consultation with FDA. The developer submits to FDA a summary of the safety and nutritional assessment that has been conducted about the bioengineered food that is intended to be introduced into commercial distribution. FDA evaluates the submission to ensure that all potential safety and regulatory questions have been addressed. FDA has recently developed a form that prompts a developer to include certain elements in the final consultation in a standard format. New Form FDA 3665 is entitled "Final Consultation for Food Derived From a New Plant Variety (Biotechnology Final Consultation)." The form, and elements that would be prepared as attachments to the form, can be submitted in electronic format.

The summary information of the safety and nutritional assessment for a new plant variety submitted to FDA (on the form and in attachments to the form) includes the following information:

- The name of the bioengineered food and the crop from which it is derived;
- A description of the various applications or uses of the bioengineered food, including animal feed uses;
- Information concerning the sources, identities, and functions of introduced genetic material;
- Information on the purpose or intended technical effect of the modification, and its expected effect on the composition or characteristic properties of the food or feed;
- Information concerning the identity and function of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product in the bioengineered crop or food derived therefrom;
- Information regarding any known or suspected allergenicity and toxicity of expression products and the basis for concluding that foods containing the expression products can be safely consumed;
- Information comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties of the same crop with special emphasis on important nutrients, and toxicants that occur naturally in the food;
- A discussion of the available information that addresses whether the potential for the food derived from a bioengineered plant to induce an allergic response has been altered by the genetic modification; and
- Any other information relevant to the safety and nutritional assessment of the bioengineered food.

In 2001, FDA contacted 5 firms that had made one or more biotechnology consultation submissions under the 1996 procedures. FDA asked each of these firms for an estimate of the hourly burden to prepare a submission under the voluntary biotechnology consultation process. Three of these firms subsequently provided the requested information. Based on this information, FDA estimated that the average time to prepare a submission for final consultation under the 1996 procedures is 150 hours (69 FR 68381, November 24, 2004). The availability of the form, and the opportunity to provide the information in electronic format, could reduce this estimate. However, as a conservative approach for the purpose of this analysis, FDA is assuming that the availability of the form and the opportunity to submit the information in electronic format will have no effect on the average time to prepare a submission for final consultation under the 1996 procedures.

Dated: February 11, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–3476 Filed 2–15–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0248]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Format and Content Requirements for Over-the-Counter Drug Product Labeling" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 13, 2010 (75 FR 49495), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0340. The approval expires on January 31, 2014. A copy of the supporting statement for this information collection is available on

the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: *February 11, 2011.*

Leslie Kux,

Acting Assistant Commissioner for Policy.

FR Doc. 2011–3475 Filed 2–15–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0543]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Importer's Entry Notice

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 March 18, 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 0910–0046. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezutto@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.

Importer's Entry Notice—(OMB Control Number 0910–0046)—Revision

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding a new chapter granting FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 801 of the FD&C Act, as amended by the Tobacco Control Act, charges the Secretary of Health and Human Services (HHS), through FDA, with the responsibility of assuring foreign origin FDA regulated foods, drugs, cosmetics, medical devices, radiological health, and tobacco products offered for import into the United States meet the same requirements of the FD&C Act as do domestic products, and for preventing products from entering the country if they are not in compliance. The discharge of this responsibility involves close coordination and cooperation between FDA (headquarters and field inspectional personnel) and the U.S. Customs Service (USCS), as the USCS is responsible for enforcing the revenue laws covering the very same products.

This collection of information was approved by OMB on August 10, 2009, and received an expiration date of August 31, 2012 (ICR Reference Number 200905–0910–006). However, because tobacco products had only recently been added to FDA's listing of regulated products when this collection of information was approved, the approved collection did not reflect information regarding tobacco products offered for import into and for prevention from them from entering the United States if they did not meet the same requirements of the FD&C Act as domestic products. The revision to this collection of information expands the universe of respondents being regulated under the FD&C Act, as amended, to include importers of tobacco products.

In the most recent OMB approval of this information collection package, FDA noted that in order to make an admissibility decision for each entry, the Agency needed four additional pieces of information that were not available from USCS's system. These data elements were the FDA Product Code, FDA country of production, manufacturer/shipper, and ultimate consignee. It was the "automated" collection of these four data elements for which OMB approval was being requested. When this package was sent to OMB for approval, FDA construed this request as an extension of the prior approval of collection of this data via a different media, i.e., paper. FDA noted that there were additional data elements which filers could provide to FDA along with other entry-related information. Doing so could result in their receiving an FDA admissibility decision more expeditiously, *e.g.,* the quantity, value, and Affirmation(s) of Compliance with Qualifier(s).

At each U.S. port of entry (seaport, landport, and airport) where foreign-origin FDA-regulated products are offered for import, FDA is notified, through Custom's Automated Commercial System (ACS) by the importer (or his agent) of the arrival of each entry. Following such notification, FDA reviews relevant data to ensure the imported product meets the standards as are required for domestic products, makes an admissibility decision, and informs the importer and USCS of its decision. A single entry frequently contains multiple lines of different products. FDA may authorize products listed on specific lines to enter the United States unimpeded, while other products in the same entry are to be held pending further FDA review/action.

An important feature developed and programmed into FDA's automated system is that all entry data passes through a screening criteria module, which makes the initial screening decision on every entry of foreign-origin FDA-regulated product. Almost instantaneously after the entry is filed, the filer receives FDA's admissibility decision covering each entry line, i.e., "MAY PROCEED" or "FDA REVIEW."

Examples of FDA's need to further review an entry may result from some products originating from a specific country or manufacturer known to have a history of problems, FDA having no previous knowledge of the foreign manufacturer and/or product, or a product import alert may have been issued, etc. The system assists FDA entry reviewers by notifying them of information, such as the issuance of import alerts, thus averting the chance that such information will be missed in their review.

Since the inception of the interface with ACS, FDA's electronic screening criteria program is applied nationwide. This eliminates problems such as "port shopping," e.g., attempts to intentionally slip products through one FDA port when refused by another, or filing entries at a port known to receive a high volume of entries. Every electronically submitted entry line of foreign-origin FDA-regulated product undergoes automated screening. The screening criteria can be set to be as specific or as broad as applicable; changes are immediately effective. This capability is of tremendous value in protecting the public in the event there is a need to