the statutory requirements of section 512(l)(3) of the act.[1] For subsequent years, the preparation of the report should take approximately 3 hours. Thus, the total cost in subsequent years would be $139.50.

Regarding the recordkeeping burden associated with this collection of information, FDA believes that most of the necessary information for the annual report required to be submitted under section 512(l)(3) of the act is already collected and maintained by animal drug manufacturers under existing requirements.

Animal drug manufacturers are already required to maintain distribution records for their drug products to comply with FDA's current good manufacturing practice regulations under § 211.196 (21 CFR § 211.96) (OMB Control No. 0910–0139), and to comply with regulations for periodic drug experience reports under § 514.80(b)(4)(i) (OMB Control No. 0910–0284). Therefore, FDA believes that manufacturers of animal drugs already possess the computers, software, and additional equipment necessary to collect and maintain the necessary records and to make reports.

Section 512(l)(3) of the act differs from § 514.80(b)(4)(i) in that it requires that records include separate information for each month of the calendar year. Under § 211.196 (OMB Control No. 0910–0139), manufacturers currently are required to maintain distribution records that include the dosage form and date the drug is distributed. Additionally, FDA believes that manufacturers already keep detailed records of the dates when antimicrobial drugs are distributed for marketing and recall purposes from which monthly reports can be prepared as part of their usual and customary practice. However, FDA estimates an additional hourly burden required by section 512(l)(3) of the act as shown in table 2 of this document.

Dated: February 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3029 Filed 2–17–10; 8:45 am]

BILLING CODE 4160–01–S

[1] BLS Occupation Employment and Wages, May 2006, by occupation, for all industries (*http://www.bls.gov*). Wage ($46.50) includes mean hourly wage of $33.22 for Standard Occupational Classification 15–0000, computer and mathematics occupations, all industries; we add 40 percent to account for benefits.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0390] (formerly Docket No. 2004N–0503)

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

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 the information collection provisions of FDA's consultation procedures for foods derived from new plant varieties, including the information collection provisions in the guidance entitled "Consultation Procedures: Foods Derived From New Plant Varieties," and in Form FDA 3665 entitled "Final Consultation For Food Derived From a New Plant Variety (Biotechnology Final Consultation)," which developers may use to prepare the final consultation in a standard format.

DATES: Submit written or electronic comments on the collection of information by April 19, 2010.

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: Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3793.

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. In the **Federal Register** of November 24, 2004 (69 FR 68379), FDA published a previous 60-day notice requesting public comment on this proposed collection of information. FDA is publishing this notice to update comments. Comments previously submitted to the Division of Dockets Management do not need to be resubmitted because all such comments that are responsive to the comment request will be summarized and responded to in the Information Collection Request, i.e. 30-day notice, submitted to OMB.

Guidance on Consultation Procedures: Foods Derived From New Plant Varieties

Since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties (the 1992 policy) (57 FR 22984, May 29, 1992), FDA has encouraged developers of new plant varieties, including those varieties that are developed through biotechnology, to consult with FDA during the plant development process to discuss possible scientific and regulatory issues that might arise. In the 1992 policy, FDA explained that, under the Federal Food, Drug, and Cosmetic Act (the act), developers of new foods (in this

document food refers to both human food and animal feed) have a responsibility to ensure that the foods they offer to consumers are safe and are in compliance with all requirements of the act (57 FR 22984 at 22985).

FDA has long regarded it to be a prudent practice for producers who use biotechnology in the manufacture or development of foods and food ingredients to work cooperatively with FDA to ensure that products derived through biotechnology are safe and comply with all applicable legal requirements. Consequently, FDA instituted a voluntary consultation process with industry. The guidance on Consultation Procedures: From New Plant Varieties (originally published in 1996 and revised October 1997; the updated version is available on FDA's Web site at *http://www.fda.gov/FoodGuidances*) fosters communication by encouraging developers to submit to FDA their evaluation of the food safety of their new plant variety. Such communication will help to ensure that any potential food safety issues regarding a new plant variety are resolved during development, and will help to ensure that all market entry decisions by the industry are made consistently and in full compliance with the standards of the act.

Description of Respondents: Respondents to this collection of information include developers of new plant varieties intended for food use.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Initial consultation	None	20	2	40	4	160
Final consultation	FDA 3665	12	1	12	150	1,800
Total						1,960

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

A. Initial Consultations

Initial consultations are generally a one-time burden, although a developer might return more than once to discuss additional issues before submitting a final consultation. As noted in its guidance to industry, FDA encourages developers to consult early in the development phase of their products, and as often as necessary. Historically, firms developing a new bioengineered plant variety intended for food use have generally initiated consultation with FDA early in the process of developing such a variety, even though there is no legal obligation for such consultation. These consultations have served to make FDA aware of foods and food ingredients before these products are distributed commercially, and have provided FDA with the information 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 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.

B. 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 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 1 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 68379 at 68381). 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 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–3028 Filed 2–17–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0070]

Agency Information Collection Activities; Proposed Collection; Comment Request; Agreement for Shipment of Devices for Sterilization

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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements relating to shipment of nonsterile devices that are to be sterilized elsewhere or are shipped to other establishments for further processing, labeling, or repacking.

DATES: Submit written or electronic comments on the collection of information by April 19, 2010.

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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@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, including each proposed extension of an existing 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.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment; (2) acknowledgment that the devices that are nonsterile are being shipped for further processing; and (3) specifications for sterilization processing.

This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products.

During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (§ 801.150(a)(2)).

The respondents to this collection of information are device manufacturers and contact sterilizers.

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