DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control; Special Emphasis Panel (SEP): Ability of Individual and Integrated Tick Management (ITM) Technologies To Reduce the Entomological Risk of Lyme Disease, Funding Opportunity Announcement (FOA) CK11–005, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

Time and Date: 12 p.m.–2 p.m., May 10, 2011 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters To Be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "Ability of Individual and Integrated Tick Management (ITM) Technologies To Reduce the Entomological Risk of Lyme Disease, FOA CK11–005."

Contact Person for More Information: Amy Yang, PhD, Scientific Review Officer, CDC, 1600 Clifton Road, NE., Mailstop E60, Atlanta, Georgia 30333, Telephone: (404) 498–2733.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: February 4, 2011.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2011–3531 Filed 2–15–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: DRA TANF Final Rule.

OMB No.: 0970–0338.

Description: When the Deficit Reduction Act of 2005 (DRA) reauthorized the Temporary Assistance for Needy Families (TANF) program, it imposed a new data requirement that States prepare and submit data verification procedures and replaced other data requirements with new versions including: the TANF Data Report, the SSP–MOE Data Report, the Caseload Reduction Documentation Process, and the Reasonable Cause/Corrective Compliance Documentation Process. The Claims Resolution Act of 2010 extended the TANF program through September 2011. We are proposing to continue these information collections without change.

Respondents: 54.

ANNUAL BURDEN ESTIMATES

Instrument or requirement	Number of respondents	Yearly submittals	Average burden hours per response	Final rule total annual burden hours
Preparation and Submission of Data Verification Procedures—§§ 261.60–261.63	54	1	640	34,560
Caseload Reduction Documentation Process, ACF–202—§§ 261.41 & 261.44	54	1	120	6,480
Reasonable Cause/Corrective Compliance Documentation Process—§§ 262.4, 262.6, & 262.7; § 261.51	54	2	240	25,920
TANF Data Report—Part 265	54	4	2,201	475,416
SSP–MOE Data Report—Part 265	29	4	714	82,824

Total Burden Hours: 625,200.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–3415 Filed 2–15–11; 8:45 am]

BILLING CODE 4184–01–P

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; Submission for Office of Management and Budget Review; 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 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–New and title "Guidance on Consultation Procedures: Foods Derived From New Plant Varieties." Also include the FDA 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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance on Consultation Procedures: Foods Derived From New Plant Varieties—(OMB Control Number 0910–NEW)

I. Background

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 FD&C 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 FD&C 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 FD&C Act.

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

In the **Federal Register** of February 18, 2010 (75 FR 7274), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one letter, containing multiple comments, in response to the notice. One comment expressed strong support for the consultation procedures, generally.

(Comment 1) One comment noted with appreciation that Form FDA 3665 will provide a standardized format and an ability to provide electronic information.

(Response) FDA agrees. As discussed elsewhere in this document, the new form will prompt developers to submit to FDA certain information in a standard format. In addition, the form and attachments can be submitted in an electronic format. FDA believes that use of the form and electronic submission will facilitate both the preparation and review of the submission because it organizes the information necessary to support the safety of the food derived from the new plant variety. FDA also expects that use of the form will decrease the overall paperwork burden on respondents.

(Comment 2) Another comment noted that the use of the new form and electronic submission of data and information for FDA's use should assure the protection of proprietary data and information submitted to FDA.

(Response) The submission to FDA may contain trade secret and commercial confidential information. Only information that is releasable under 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act (21 U.S.C. 331(j)) and would be protected from disclosure under sections 552(a) and (b) of the Freedom of Information Act (5 U.S.C. 552(a) and (b)).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	FDA Form No.	Number 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.

II. 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 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]

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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