DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Child Care Report for High Performance Bonus.

OMB No.: 0970–0255.

Description: The Personal Responsibility and Work Opportunity Reconciliation Act of 1996, Pub. L. 104–193, established the Temporary Assistance for Needy Families (TANF) program under title IV–A of the Social Security Act (the Act), 42 U.S.C. 401 *et seq.* Section 403(a)(4) of the Act requires the Secretary to award bonuses to ''high performing States.'' (Indian tribes are not eligible for these bonuses.) The term ''high performing States'' is defined in section 403(a)(4) of the Act to mean a State that is most successful in achieving the purposes of the TANF program as specified in section 401(a) of the Act.

The final rule covering the TANF high performance bonuses to States in FY 2002 and beyond was published August 30, 2000 (65 FR 52814) followed by an interim final rule published May 10, 2001 (66 FR 23854). The final and interim final rules set forth how the Child Care Bureau (CCB) will compute scores and rank States won the three components, *i.e.*, Accessibility, Affordability, and Quality, that comprise the child care measure.

In FY 2002, CCB measured State performance on a composite ranking of two components, *i.e.*, Accessibility and Affordability (based on FY 2001 performance data). No additional reporting burden was required since the data/information for the Accessibility and Affordability components are reported under the Child Care Development Fund program (ACF Reports 800 and 801). However, there was a reporting burden (related to the Quality component) for the information States submitted if they wished to compete on the child care measure beginning in FY 2003 and again in FY 2004 (based on FY 2002 and FY 2003 performance data, respectively). The same requirements must be met for States wishing to compete on the child care measure for FY 2005 (based on FY 2004 performance data). The information includes:

(1) All age-specific rates for children 0–13 years of age reported by the child day care centers and family day care homes responding to the State's market rate survey; and

(2) The provider's county or, if the State uses multi-county regions to measure market rates or set maximum payment rates, the administrative region.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–801	56	0.5	40	1,120

Estimated Total Annual Burden Hours. 1,120.

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: *grjohnson@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.

Dated: November 17, 2004.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 04–25994 Filed 11–23–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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, 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 for the Guidance on Consultation Procedures; Foods Derived From New Plant Varieties.

DATES: Submit written or electronic comments on the collection of information by January 24, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments.* 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

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; Foods Derived From New Plant Varieties (Originally published in 1996 and revised October 1997, the updated version is available on FDA's Internet site at *http://www.cfsan.fda.gov/~lrd/consulpr.html*) 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.

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

TABLE 1.—ESTIMATED REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Initial consultation	20	2	40	4	160
Final consultation	12	1	12	150	1,800
Annual one time burden hours					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, the food industry generally has initiated consultation with FDA early in the process of developing a new bioengineered plant variety, even though there is no legal obligation to do so. 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.

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.

Summary information of the safety and nutritional assessment for a new plant variety submitted to FDA 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 five 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 is estimating that the average time to prepare a submission for final consultation under the 1996 procedures is 150 hours.

Dated: November 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–26048 Filed 11–19–04; 1:52 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0369]

Draft Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.'' The draft guidance, when finalized, is intended to provide recommendations to developers of new plant varieties, in particular bioengineered plants, on the early food safety evaluation of new non-pesticidal proteins. The draft guidance describes procedures for submitting an early food safety evaluation of such proteins to the agency.

DATES: Submit written or electronic comments concerning the draft guidance and the collection of information provisions by January 24, 2005.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' to Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1165. Send one self-adhesive address label to assist that office in processing your request, or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments concerning the draft guidance and the collection of information provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Mary D. Ditto, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1165, FAX 301–436–2965, e-mail: *mditto@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In a document in the **Federal Register** of August 2, 2002 (67 FR 50578), the U.S. Office of Science and Technology Policy (OSTP) proposed Federal actions to update field test requirements and to establish early voluntary food safety evaluations for new proteins produced by bioengineered plants. Rapid developments in genomics are resulting in dramatic changes in the way new plant varieties are developed and commercialized. Scientific advances are expected to accelerate over the next decade, leading to the development and commercialization of a greater number and diversity of bioengineered crops. As the number and diversity of field tests for bioengineered plants increase, the likelihood that cross-pollination due to pollen drift from field tests to commercial fields and commingling of seeds produced during field tests with commercial seeds or grain may also increase. This could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated through FDA's voluntary consultation procedures for foods derived from new plant varieties (referred to as ''biotechnology consultation'' in the case of bioengineered plants).[1] FDA is issuing a draft guidance document to address this possibility.

This draft guidance describes the procedure for early food safety evaluation of new proteins produced by new plant varieties that are under

[1] Guidance on Consultation Procedures: Foods Derived from New Plant Varieties can be found at *http://www.cfsan.fda.gov/~lrd/consulpr.html*.