3,800; *Total Annual Responses:* 3,800; *Total Annual Hours:* 608,000.

To obtain copies of the supporting statement and any related forms for these paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB Desk Officer at the address below, no later than 5 p.m. on *March 13, 2006.* OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 3, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–1819 Filed 2–9–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–359, 360, R–55; CMS–368, R–144; and CMS–643]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Information Collection Requirements at 42 CFR 485.56, 485.58, 485.60, 485.64, 485.66 and 410.105; *Use:* In order for a provider to participate in the Medicare program as a CORF, a provider must meet the Federal conditions of participation. The form CMS–359 is utilized as an application for facilities wishing to participate in the Medicare/Medicaid program as CORFs. This form initiates the process of obtaining a decision as to whether the conditions of participation are met. The form CMS–360 is an instrument used by the State survey agency to record data collected in order to determine the provider compliance with individual conditions of participation and to report it to the Federal government; *Form Numbers:* CMS–359, 360, R–55 (OMB#: 0938–0267); *Frequency:* Reporting—On occasion; *Affected Public:* State, Local, or Tribal government and Business or other for-profit; *Number of Respondents:* 630; *Total Annual Responses:* 630; *Total Annual Hours:* 300,046.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Medicaid Drug Rebate; *Use:* Section 1927 of the Social Security Act requires each State Medicaid agency to report quarterly prescription drug utilization information to drug manufacturers and to the Centers for Medicare and Medicaid Services. As part of this information, the State Medicaid agencies are required to report the total Medicaid rebate amount they claim they are owed by each drug manufacturer for each covered prescription drug product each quarter; *Form Numbers:* CMS–368, R–144 (OMB#: 0938–0582); *Frequency:* Reporting—Quarterly; *Affected Public:* State, Local, or Tribal government; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 9,389.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations at 42 CFR 442.30 and 488.26; *Use:* In order to participate in the Medicare program, a hospice must meet certain Federal health and safety conditions of participation. This form is used by State surveyors to record data about a hospice's compliance with these conditions of participation in order to initiate the certification or recertification process; *Form Number:* CMS–643 (OMB#: 0938–0379); *Frequency:* Reporting—Annually; *Affected Public:* Not-for-profit institutions and Business or other for-profit; *Number of Respondents:* 2,293; *Total Annual Responses:* 475; *Total Annual Hours:* 238.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received at the address below, no later than 5 p.m. on April 11, 2006. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto (CMS–359, 360, R–55; CMS–368, R–144; and CMS–643) Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: January 31, 2006.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E6–1820 Filed 2–9–06; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0369]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

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 (the PRA).

DATES: Fax written comments on the collection of information by March 13, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

Since 1992, when FDA issued its Statement of Policy: Foods Derived from New Plant Varieties (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 early in the development process to discuss possible scientific and regulatory issues that might arise. The current guidance continues to foster early communication by encouraging developers to submit to FDA their evaluation of the food safety of their new protein. Such communication helps to ensure that any potential food safety issues regarding a new protein in a new plant variety are resolved early in development, prior to any possible inadvertent introduction into the food supply of material from that plant variety.

FDA believes that any food safety concern related to such material entering the food supply would be limited to the potential that a new protein in food from the plant variety could cause an allergic reaction in susceptible individuals or could be a toxin. This guidance describes the procedures for early food safety evaluation of new proteins in new plant varieties, including bioengineered food plants, and the procedures for communicating with FDA about the safety evaluation.

In the **Federal Register** of November 24, 2004 (69 FR 68381), FDA published a notice of availability with a 60-day comment period requesting public comment on the collection of information in FDA's draft guidance document titled, ''Guidance for Industry: Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.''

Nonresponsive comments

FDA received approximately 5,000 letters in response to the November 24, 2004, notice. However, many of these letters contained comments that were not responsive to the PRA questions. For example, several comments expressed the following opinions: The collection of information was insufficient to ensure safety; the agency might not be able to commit sufficient resources to performing early food safety reviews without having to redirect resources from other tasks; the decision should not be left to the developer regarding when to submit an early food safety evaluation to the agency; and the objectivity and scientific expertise of the individuals reviewing the information may be inadequate.

(Response) These comments are general comments directed to the adequacy of the guidance, rather than specific comments relevant to the collection of information; therefore, these non-responsive comments will not be addressed in this document.

Responsive comments

FDA received several letters with specific comments responsive to the comment request concerning the proposed information collection in the notice. The comments and FDA's responses follow.

(Comment 1) Several comments were supportive of the information collection, stating that the information collection was necessary for FDA to fulfill statutory requirements to protect the safety of the food supply. Relevant to the minimization of burden, several of these comments also noted that the information collection was appropriately limited in scope to prevent duplicative submissions among Federal agencies.

(Response) These comments provide support for the utility of the information collection and confirm that the collection will not result in a duplicative information collection among Federal agencies.

(Comment 2) One comment suggested that FDA should minimize the burden on developers by referencing in the guidance the availability of public protein databases that could be useful in the evaluation of allergen or toxin homology.

(Response) FDA does not want to reference or list the various databases because to do so would imply that FDA is endorsing any or all of them. FDA finds that there are several databases in the public domain that are easily obtained through the internet, are known in the scientific community, and are in common use by developers of bioengineered crops.

(Comment 3) One comment suggested that FDA could minimize the burden of the proposed collection of information by clarifying that a weight of the evidence approach is applied to the assessment of potential allergenicity of a new protein. The comment further suggested that alternative methods and protocols be considered in the evaluation of the allergenicity of new proteins.

(Response) FDA's guidance does not state that a weight of the evidence approach will be applied to the evaluation. The guidance describes a case-by-case evaluation that recognizes that different pieces of information may have varying importance for the food safety evaluation depending on the characteristics of the protein. As stated in the guidance, developers are free to use alternative approaches in their evaluations. The comment fails to explain how a weight of the evidence approach would reduce the burden under the PRA.

(Comment 4) One comment suggested as an approach to minimize burden on developers that FDA treat highly similar proteins as a family of proteins, if they differ only by a few amino acids but retain the same function, rather than evaluating each protein individually, though the comment further suggests that certain aspects of a protein may be evaluated individually.

(Response) FDA notes that the guidance is intended to consider specific proteins, not protein families. FDA further notes that even small changes in amino acid sequence may alter a protein, and these small differences could also have implications for food safety. However, if there is relevant information contained in a previous submission, that information can be incorporated by reference into a current submission for a new protein evaluation.

(Comment 5) One comment suggested as a means of minimizing burden of the proposed collection of information that

FDA provide standard forms or formats for certain elements of the submission (e.g., bioinformatics reports). The comment also suggested minimizing burden by making greater use of electronic submissions.

(Response) FDA has considered the use of standardized forms or formats and at this time does not believe that their use would reduce the burden of the information collection. The use of standardized forms could discourage alternative approaches for the presentation of data in an evaluation that might more clearly or thoroughly set forth the data. Developers will have access to the forms and formats used by previous submitters and are free to use them; thus, at this time we do not perceive a need for a standardized form. Based on its experience in evaluation of submissions FDA will in the future revisit whether the use of standardized forms and formats would be advantageous to developers.

With respect to electronic submissions, FDA states in the guidance that electronic submissions are acceptable, but one paper copy is also requested. Efforts are underway at FDA to convert in the future to a submission process that is entirely electronic.

(Comment 6) One comment stated that a way to enhance the quality, utility, and clarity of the information to be collected is to follow guidance available from the Codex Alimentarius. Although the comment did not specify which guidance from the Codex Alimentarius FDA should follow, FDA believes that the comment is referring to the Codex Alimentarius ''Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants'' (CAC/GL 45–2003) (the Codex Plant Guideline), containing ''Annex: Assessment of Possible Allergenicity'' (the Codex Allergenicity Annex). The comment also stated that FDA should make Codex guidance a mandatory part of its guidance.

(Response) FDA agrees in part and disagrees in part. FDA notes that its recommendations in this guidance are consistent with the approach recommended in the Codex Plant Guideline. In fact, FDA references the Codex Plant Guideline as a resource to be consulted by a developer in evaluating the food safety of a new protein. However, FDA notes that the Codex Plant Guideline addresses a broad range of issues associated with food safety assessment of food derived from bioengineered plants. While FDA's guidance is consistent with the Codex Plant Guideline, it does not address the entire broad range of issues as that document. FDA's guidance is focused on the food safety issues that might arise from the intermittent, low-level presence of material from a plant being developed for food and feed use. FDA believes that any potential risk from the intermittent, low level presence of such material in the food supply would be limited to the food safety of the new proteins. FDA references the Codex Plant Guideline, paragraphs 34–43 under Expressed Substances (non-nucleic acid substances) and the Codex Allergenicity Annex, for that component of the safety review.

FDA disagrees with the comment's suggestion that the agency make the Codex Plant Guideline a mandatory part of its guidance. While FDA believes that the Codex Plant Guideline and the Codex Allergenicity Annex are useful documents, it recognizes that other approaches may also be appropriate.

(Comment 7) One comment stated that while the information to be collected is essential and important for FDA to obtain, the information is inadequate to fulfill FDA's ''stated and mandated goals,'' and therefore it is of questionable utility.

(Response) FDA disagrees. The guidance is properly focused on the food safety assessment of a new protein produced in a new plant variety when there might be a low level, intermittent presence of material from a plant being developed for food. Although the commenter would like more information to be presented for FDA review at this stage, FDA notes that more information is not necessary because the information that the guidance recommends a developer collect and present to FDA as part of a food safety evaluation of a protein is adequate for the specific assessment that FDA is making at this stage. FDA recommends that a broader scope of information be presented to FDA for review at subsequent evaluation stages. For example, when a developer utilizes the recommendations articulated in FDA's guidance entitled, ''Consultation Procedures for New Plant Varieties'' (available at *http://www.cfsan.fda.gov/~lrd/consulpr.html*), FDA expects that significantly more information will be presented during the consultation.

(Comment 8) Several comments challenged the accuracy of FDA's estimate of the burden of the proposed collection of information. These comments opined that FDA should collect more extensive information than what is proposed in the guidance, and they concluded, therefore, that FDA had underestimated the burden of the proposed information collection. The comments did not challenge the accuracy of the burden estimate for the information as proposed in the guidance.

(Response) FDA notes that the comments did not challenge the accuracy of FDA's estimate, rather they challenged what FDA recommends in the guidance. FDA believes that the estimate of the burden of the proposed collection of information is accurate.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
First four data components	20	1	20	4	80
Two other data components	20	1	20	16	320
Total					400

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

One Time Burden

Completing an early food safety evaluation for a new protein from a new plant variety will be a one-time burden (one evaluation per new protein). FDA cannot know how many developers will choose to complete an early food safety evaluation for their new plant protein. Many developers of novel plants may choose not to submit an evaluation because the field testing of a plant containing a new protein is conducted

in such a way (e.g., on such a small scale, or in such isolated conditions, etc.) that cross-pollination with traditional crops or commingling of plant material is not likely to be an issue. Also, other developers may have previously communicated with FDA about the food safety of a new plant protein, for example, when the same protein was expressed in a different crop.

FDA scientists predict that this draft guidance will generate about 20 to 150 early food safety evaluations yearly. While there is uncertainty as to the number of developers who will choose to submit an evaluation, FDA estimates that the annual number of early food safety evaluations will be closer to the lower bound estimate of 20 evaluations rather than the upper bound estimate of 150 evaluations. This estimation is supported by the fact that on average there have been nine initial biotechnology consultations per year. An initial biotechnology consultation has traditionally been the first discussion between a developer and FDA about a food made from a new bioengineered plant variety; it is usually bioengineered varieties of plants that are the subject of a consultation with FDA.

Evaluation Components

The early food safety evaluation for new proteins includes six main data components. Four of these data components are easily and quickly obtainable, having to do with the identity and source of the protein. FDA estimates that completing these data components will take about 4 hours per evaluation. In table 1 of this document, row 1 shows that for 20 evaluations, the total burden for these 4 data components is 80 hours.

Two data components ask for original data to be generated. One data component consists of a bioinformatics analysis which can be performed using publicly available databases. The other data component involves 'wet' lab work to assess the new protein's stability and the resistance of the protein to enzymatic degradation using appropriate in vitro assays (protein digestibility study).

The paperwork burden of these two data components consists of the time it takes the company to put together the information on these two data components to submit to FDA. We estimate that these two data components will take 16 hours to complete (8 hours for each component). In Table 1 of this document, row 2 shows that for 20 evaluations, the total burden for these two data components is 320 hours.

Dated: February 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1806 Filed 2–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0296]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Financial Disclosure by Clinical Investigators

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 13, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Financial Disclosure by Clinical Investigators—(OMB Control Number 0910–0396)—Extension

Respondents are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic and medical device firms. The applicant will incur reporting costs in order to comply with the final rule. Applicants will be required to submit, for example, the complete list of clinical investigators for each covered study, not employed by the applicant and/or sponsor of the covered study, and either certify to the absence of certain financial arrangements with clinical investigators or disclose the nature of those arrangements to FDA and the steps taken by the applicant or sponsor to minimize the potential for bias. The clinical investigator will have to supply information regarding financial interests or payments held in the sponsor of the covered study. FDA has said that it has no preference as to how this information is collected from investigators and that sponsors/applicants have the flexibility to collect the information in the most efficient and least burdensome manner that will be effective. FDA estimated that the total reporting costs of sponsors would be less than $450,000 annually. Costs could also occur after a marketing application is submitted if FDA determines that the financial interests of an investigator raise significant questions about the integrity of the data.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
54.4(a)(1) and (a)(2)	1,000	1	1,000	5	5,000
54.4(a)(3)	100	1	100	20	2,000
54.4	46,000	.25	11,500	.1	11,500
Total					18,500

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