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FDA scientists predict that this draft guidance will generate about 20 to 150 early food safety evaluations yearly.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]

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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.

The sponsors of covered studies will be required to maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. This time is consistent with the current recordkeeping requirements for other information related to marketing applications for human drugs, biologics, and medical devices. Currently, sponsors of covered studies must maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to clinical investigators' file.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Recordkeeper	Total Hours
54.6	1,000	1	1,000	.25	250
Total					250

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

In the **Federal Register** of August 25, 2005 (70 FR 49928), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. No comments were received regarding this information collection.

Dated: February 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1807 Filed 2–9–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0425]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

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: 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.

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions—(OMB Control Number 0910–0183)—Extension

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Under part 10 (21 CFR part 10), § 10.30 sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (submission of documents to the Division of Dockets Management (DDM)), a citizen petition requesting the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups.

Section 10.33, issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner in a petition submitted under § 10.25 (initiation of administrative proceedings). A petition for reconsideration must contain in a well-organized format a full statement of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. The respondent must submit a petition no later than 30 days after the decision has been made. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting a reconsideration of a matter from the Commissioner.

Section 10.35, issued under section 701(a) of the act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to DDM), the Commissioner to stay the effective date of any administrative action.

Such a petition must provide the following information: (1) The decision involved; (2) the action requested, including the length of time for which a stay is requested; and (3) a statement