trigger approximately 186 efficacy supplements, each one requiring approximately 196 hours to revise the labeling in the application, totaling 36,456 hours. (As stated in the final rule, in addition to this burden, a minimal annual reporting burden (fewer than 7) will continue indefinitely).

Burden Associated with Revised Labeling for Efficacy Supplements for Generic Drug Products (§ 201.57) (Table 2)

Based on the projected data estimated in the final rule, beginning in year 3 and continuing throughout the 10-year period analyzed, approximately 42 generic applicants per year must submit labeling supplements. Approximately 336 already approved generic drug applications must submit labeling supplements over the 10-year period after the effective date of the rule. The time required to revise and submit this labeling to FDA is approximately 27 hours per application, totaling 9,072 hours. (As stated in the final rule, in addition to this burden, a minimal annual reporting burden associated with a very small number of generic applications referencing older drugs may continue indefinitely).

C. Capital Costs

As discussed in the final rule, a small number of carton-enclosed products may require new packaging to accommodate longer inserts. As many as 5 percent of the existing products affected by the final rule (i.e., products with new efficacy supplements, products approved in the 5 years prior to the effective date of the rule, and affected abbreviated new drug applications) may require equipment changes at an estimated cost of $200,000 each product.

In the **Federal Register** of September 29, 2008 (73 FR 56592), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received relating to the paperwork.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN FOR NEW DRUG APPLICATIONS[1]

Category (21 CFR Section)	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Annual Burden for Labeling Requirements in §§ 201.56 and 201.57	85	1.26	107	3,349	358,343
Total					358,343

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDENS FOR LABELING REVISIONS TO ALREADY-APPROVED DRUG PRODUCTS[1]

Category (21 CFR Section)	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
Burden associated with revised labeling for applications approved within 5 years prior to June 30, 2006 (§ 201.57)	172	2	344	196	67,424
Burden associated with revised labeling for efficacy supplements submitted on or after June 30, 2006 (§§ 201.56(d) and 201.57)	172	1.08	186	196	36,456
Burden associated with revised labeling for efficacy supplements for generic drug products (§ 201.57)	42	8	336	27	9,072
Total					112,952

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

Dated: December 24, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–175 Filed 1–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0657]

Agency Information Collection Activities; Proposed Collection; 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 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

the information collection provisions of the guidance document entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use.''

DATES: Submit written or electronic comments on the collection of information by March 10, 2009.

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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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.

Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use (OMB Control Number 0910–0583—Extension)

Since May 29, 1992, when FDA issued a policy statement on foods derived from new plant varieties, 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 (57 FR 22984). The guidance entitled ''Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use'' 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. The 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.

The respondents to this collection of information are 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]

	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.

FDA estimates the annual total hour burden for this collection of information to be 400 hours. This estimate is based on early food safety evaluations submitted in the past 3 years. FDA's estimate of the time that it would take a respondent to prepare the data components of the early food safety evaluation submission is based on the agency's experience with similar submissions.

Completing an early food safety evaluation for a new protein from a new plant variety is a one-time burden (one evaluation per new protein). Based on its experience over the past 3 years, FDA estimates that approximately 20 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.

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 assemble 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–213 Filed 1–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0081] (formerly Docket No. 2006D–0297)

International Conference on Harmonisation; Guidance on Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the International Conference on Harmonisation Regions; Annex on Test for Extractable Volume of Parenteral Preparations General Chapter; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 2: Test for Extractable Volume of Parenteral Preparations General Chapter.'' The guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The guidance provides the results of the ICH Q4B evaluation of the Test for Extractable Volume of Parenteral Preparations General Chapter harmonized text from each of the three pharmacopoeias (United States, European, and Japanese) represented by the Pharmacopoeial Discussion Group (PDG). The guidance conveys recognition of the three pharmacopoeial methods by the three ICH regulatory regions and provides specific information regarding the recognition. The guidance is intended to recognize the interchangeability between the local regional pharmacopoeias, thus avoiding redundant testing in favor of a common testing strategy in each regulatory region. In the **Federal Register** of February 21, 2008 (73 FR 9575), FDA made available a guidance on the Q4B process entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions.''

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to assist the office in processing your requests. Submit written comments on the guidance 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.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Robert H. King, Sr., Center for Drug Evaluation and Research (HFD–003), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 4150, Silver Spring, MD 20993–0002, 301–796–1242; or

Christopher Joneckis, Center for Biologics Evaluation and Research (HFM–1), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–0373.

Regarding the ICH: Michelle Limoli, Office of International Programs (HFG–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4480.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health