TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Survey	1,000	1	1,000	.167	167
Total					365

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

FDA's burden estimate is based on prior experience with consumer surveys very similar to this proposed study.

Experimental Study on Allergen Labeling of Food Products

As previously above, under section 903(b)(2) of the act, FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the Nation's food supply. FDA is planning to conduct an experimental study about allergen labeling of food products under this authority. The Experimental Study on Allergen Labeling of Food Products will collect information to gauge the impact of certain changes to the food label with respect to information about allergenic ingredients. This data collection is needed to satisfy some of the requirements of the FALCPA, including the requirement that FDA provide data on consumer preferences with regard to allergen labeling in a report to Congress. In particular, section 204.4 of the FALCPA asks FDA to describe in the report ''* * *how consumers with food allergies or the caretakers of consumers would prefer that information about the risk of cross-contact be communicated on food labels as determined by using appropriate survey mechanisms.'' The allergen labeling experiment will supplement data collected by the Allergen Labeling of Food Products Consumer Preference Survey. In addition, the experiment will address other issues pertinent to allergen labeling changes mandated by the FALCPA. The experimental study data will be collected using an Internet panel of approximately 600,000 people who will be screened (through self-report) for food allergy, and food allergy caregiver status. Participation in the allergen experimental study is voluntary.

FDA estimates the burden of the Experimental Study on Allergen Labeling of Food Products collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Screener	600,000	1	600,000	.0028	1,680
Pre-test	30	1	30	.167	5
Experiment	9,000	1	9,000	.167	1,503
Total					3,188

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

FDA's burden estimate is based on prior experience with internet panel experiments similar to the study proposed here.

Dated: January 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–1395 Filed 1–25–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0386]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical Current Good Manufacturing Practice

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 February 25, 2005.

ADDRESSES: The Office of Management and Budget (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 L. 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.

Title: Draft Guidance for Industry on Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP

Description: The draft guidance is intended to provide information to manufacturers of veterinary and human drugs, including human biological drug products, on how to resolve disputes of scientific and technical issues relating to current good manufacturing practice (CGMP). Disputes related to scientific and technical issues may arise during FDA inspections of pharmaceutical manufacturers to determine compliance with CGMP requirements, or during FDA's assessment of corrective actions undertaken as a result of such inspections. The draft guidance provides procedures that will encourage open and prompt discussion of disputes and lead to their resolution. The draft guidance describes procedures for raising such disputes to FDA's Office of Regulatory Affairs and center levels and for requesting review by the dispute resolution (DR) panel.

When a scientific or technical issue arises during an FDA inspection, the manufacturer should initially attempt to reach agreement on the issue informally with the investigator. Certain scientific or technical issues may be too complex or time-consuming to resolve during the inspection. If resolution of a scientific or technical issue is not accomplished through informal mechanisms before the issuance of the Form FDA 483, the manufacturer can formally request DR and can use the formal two-tiered DR process described in the draft guidance.

Tier-one of the formal DR process involves scientific or technical issues raised by a manufacturer to the ORA and center levels. If a manufacturer disagrees with the tier-one decision, tier-two of the formal DR process would then be available for appealing that decision to the DR Panel.

If a manufacturer disagrees with the scientific or technical basis for an observation listed by an investigator on a Form FDA 483, the manufacturer can file a written request for formal DR with the appropriate ORA unit as described in the draft guidance. The request for formal DR should be made within 10 days of the completion of an inspection, and should include all supporting documentation and arguments for review, as described in the following paragraphs. If a manufacturer disagrees with the tier-one decision in the formal DR process, the manufacturer can file a written request for formal DR by the DR Panel. The manufacturer should provide the written request for formal DR and all supporting documentation and arguments, as described in the following paragraphs, to the DR Panel within 60 days of receipt of the tier-one decision.

All requests for formal DR should be in writing and include adequate information to explain the nature of the dispute and to allow FDA to act quickly and efficiently. Each request should be sent to the appropriate address listed in the draft guidance and include the following:

- Cover sheet that clearly identifies the submission as either a request for tier-one DR or a request for tier-two DR;
- Name and address of manufacturer inspected (as listed on Form FDA 483);
- Date of inspection (as listed on Form FDA 483);
- Date the Form FDA 483 issued (from the Form FDA 483);
- FDA Establishment Identification (FEI) Number, if available (from Form FDA 483);
- FDA employee names and titles that conducted inspection (from Form FDA 483);
- Office responsible for the inspection, e.g., district office, as listed on the Form FDA 483;
- Application number if the inspection was a preapproval inspection;
- Comprehensive statement of each issue to be resolved:

Identify the observation in dispute.

Clearly present the manufacturer's scientific position or rationale concerning the issue under dispute with any supporting data.

State the steps that have been taken to resolve the dispute, including any informal DR that may have occurred before the issuance of the Form FDA 483.

Identify possible solutions.

State expected outcome.

- Name, title, telephone and fax number, and e-mail address (as available) of manufacturer contact.

Description of Respondents: Pharmaceutical manufacturers of veterinary and human drug products and human biological drug products.

Burden Estimate: FDA has reviewed the total number of informal disputes that currently arise between manufacturers and investigators (and FDA district offices) when a manufacturer disagrees with the scientific or technical basis for an observation listed on a Form FDA 483. FDA estimates that approximately 12 such disputes occur annually. FDA believes that the number of requests for formal DR under the draft guidance would be higher because manufacturers have expressed reluctance to dispute with the agency scientific or technical issues raised in an investigation in the absence of a formal mechanism to resolve the dispute. In addition, manufacturers have requested the formal mechanisms in the draft guidance to facilitate the review of such disagreements. Therefore, FDA estimates that approximately 25 manufacturers will submit approximately 25 requests annually for a tier-one DR. FDA also estimates that approximately five manufacturers will appeal approximately five of these requests to the DR Panel (request for tier-two DR).

Based on the time it currently takes manufacturers to prepare responses to FDA concerning issues raised in a Form FDA 483, FDA estimates that it will take manufacturers approximately 30 hours to prepare and submit each request for a tier-one DR and approximately 8 hours to prepare and submit each request for a tier-two DR.

Based on the methodology and assumptions in the previous paragraphs, table 1 of this document provides an estimate of the annual reporting burden for requests for a tier-one DR and requests for a tier-two DR under the draft guidance.

ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Requests for Tier-One Dispute Resolution	25	1	25	30	750

ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
≤Requests for Tier-Two Dispute Resolution	5	1	5	8	40
Total					790

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

In the **Federal Register** of September 5, 2003 (68 FR 52777), FDA announced the availability of a draft guidance for industry entitled ''Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP.'' The notice requested comments on the information collection estimates within 60 days. No comments were received on the information collection estimates. This document requests comments on the information collection burden that FDA estimates will result from the draft guidance.

The draft guidance was drafted as part of FDA's initiative ''Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach,'' which was announced in August 2002. The initiative focuses on FDA's current CGMP program and covers the manufacture of veterinary and human drugs, including human biological drug products. The agency formed the DR Working Group comprising representatives from ORA, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, and the Center for Veterinary Medicine. The working group met weekly on issues related to the DR process and met with stakeholders in December 2002 to seek their input.

The draft guidance was initiated in response to industry's request for a formal DR process to resolve differences related to scientific and technical issues that arise between investigators and pharmaceutical manufacturers during FDA inspections of foreign and domestic manufacturers. In addition to encouraging manufacturers to use currently available DR processes, the draft guidance describes a formal two-tiered DR process that provides a formal mechanism for requesting review and decision on issues that arise during inspections:

- Tier-one of the DR process provides a mechanism to raise scientific or technical issues to the ORA and center levels.
- Tier-two of the DR process provides a mechanism to raise scientific or technical issues to the agency's DR Panel for Scientific and Technical Issues Related to Pharmaceutical CGMP (DR Panel).

The draft guidance also covers the following topics:

- The suitability of certain issues for the formal DR process, including examples of some issues with a discussion of their appropriateness for the DR process.
- Instructions on how to submit requests for formal DR and a list of the supporting information that should accompany these requests.
- Public availability of decisions reached during the DR process to promote consistent application and interpretation of drug quality-related regulations.

Dated: January 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0004]

Draft Guidance for Industry on Nonclinical Safety Evaluation of Drug Combinations; 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 ''Nonclinical Safety Evaluation of Drug Combinations.'' The guidance provides recommendations on nonclinical approaches to support the clinical study and approval of fixed-dose combination products (FDCs), copackaged products, and adjunctive therapies.

DATES: Submit written or electronic comments on the draft guidance by April 26, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Abby Jacobs, Center for Drug Evaluation and Research (HFD–540), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Safety Evaluation of Drug Combinations.'' Drug combinations include FDCs, copackaged products, and adjunctive therapies. An FDC is a product in which two or more separate drug components (active pharmaceutical ingredients) are combined in a single dosage form. A copackaged product consists of two or more separate drug products in their final dosage form, packaged together with appropriate labeling to support the combination use. An adjunctive therapy refers to the situation in which a patient is maintained on a second drug product that is used together with (i.e., in adjunct to) the primary treatment, although the relative doses are not fixed and the drugs need not be given at the same time. Adjunctive therapy products may or may not be labeled for concomitant use. The guidance discusses all three types of drug combinations. However, it is only intended to describe general guiding principles. To receive more detailed