enable the public to understand the proposal so that comments can then be made to the agency based on full knowledge of the proposal.

FDA responds to the comment by stating in the 30-day **Federal Register** notice and in the information collection requirement adequate details about the purpose were added to enable the public to understand the purpose of the proposal. Therefore, FDA is not going to reissue the 60-day **Federal Register** notice, but has considered and responded to all the comments received.

The third section of the comment states that risk management requires the involvement of all stakeholders, including government, industry, health-care professionals, and patients. The role of medical product sponsor appears to be left out of the process.

FDA's response is that medical product sponsors as a stakeholder was omitted inadvertently from the 60-day **Federal Register** notice seeking public comment. They will be included in the 30-day **Federal Register** notice announcing FDA's submission of this information collection to OMB as well as in the justification package sent to OMB.

The fourth section of the comment states that it is unclear to whom the surveys will be directed. Although the notice identifies general groups, there is no discussion of how members of these groups will be identified to participate in the surveys.

The FDA reply is that the agency will determine which groups to which groups will be asked to participate in each particular survey based on the type of medical product problem that occurred. For instance, if the problem dealt with clinical laboratory devices and a perceived problem with antibody assays for detection of the herpes virus and laboratory information systems mixing up pathology reports, FDA would survey the members of the American Society of Microbiology Division C and facilities that use such information that is retrieved from the MedSun system.

Section five deals with the voluntary nature of the surveys risks the collection of potentially confounded, biased, and unconfirmed information on which, according to the notice, the agency intends to ''take: appropriate public health or regulatory action.''

FDA responds that usually it expects a 70 percent response rate. The impact of a lower response rate to these surveys will be considered before FDA takes action to improve the response rate. FDA may determine that quicker action—development of a public position paper—can be taken based on consistent responses from each of the surveys conducted. If there is a low response rate with no clear pattern of response, the national organization representing that stakeholder group will send a letter to all respondents reminding them to fill out the survey form.

FDA proposes to draw purposeful samples for these surveys. Since the survey data will not be used for estimates of incidence, there is no need for a probability sample. Because these proposed data collections are qualitative, not quantitative, and because FDA resources for processing incoming data limited, FDA proposes to keep these data collection efforts to a manageable size.

The response universe will be kept to those stakeholders that have been identified as appropriate respondents. These will be groups that focus on those specialties and have experience and expertise in those areas.

The sixth and final section of the comment stated that the notice doesn't address the mechanism by which the surveys will produce ''rapid responses'' from those surveyed. Whether the surveys will be conducted by mail, facsimile, telephone, or the Internet, there is a need to validate the source(s) and medical accuracy of the information provided. One of the hallmarks of responsible risk management is confirmation of the information upon which decisions are based. Decision should not be based on information gathered in haste if/when the source and validity of the data have not been confirmed.

FDA's response is depending on the criticality of the survey and the speed in which the data needs to be returned to FDA, respondents can use mail, faxes, or e-mail for their survey responses. More use of Internet based surveys will be made in the future.

FDA will employ great care in determining the validity of the information received. This will be done through the design of the survey instruments and keeping identifiers for followup if the Center has concerns about the data received. After the data has been verified, the respondents identifying information will be deleted.

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 |
|---|---|---|---|---|
| 200 | 30 (maximum) | 6,000 | .5 | 3,000 |

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

FDA projects 30 emergency risk related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours (30 minutes) per response.

These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only one time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours (30 minutes) for a respondent to gather the requested information and fill in the answers.

Dated: October 9, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–26324 Filed 10–15–02; 8:45 am]

BILLING CODE 4160–01–S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02D–0303]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by November 15, 2002.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (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.

**Guidance for Industry on Formal Dispute Resolution; Appeals Above the Division Level (OMB Control Number 0910–0430)—Extension**

This information collection approval request is for an FDA guidance on the process for formally resolving scientific and procedural disputes in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) that cannot be resolved at the division level. The guidance describes procedures for formally appealing such disputes to the office or center level and for submitting information to assist center officials in resolving the issue(s) presented. The guidance provides information on how the agency will interpret and apply provisions of the existing regulations regarding internal agency review of decisions § 10.75 (21 CFR 10.75) and dispute resolution during the investigational new drug application (IND) process (21 CFR 312.48) and the new drug application/abbreviated new drug application (NDA/ANDA) process (21 CFR 314.103). In addition, the guidance provides information on how the agency will interpret and apply the specific Prescription Drug User Fee Act (PDUFA) goals for major dispute resolution associated with the development and review of PDUFA products.

Existing regulations, which appear primarily in parts 10, 312, and 314 (21 CFR parts 10, 312, and 314), establish procedures for the resolution of scientific and procedural disputes between interested persons and the agency, CDER, and CBER. All agency decisions on such matters are based on information in the administrative file (§ 10.75(d)). In general, the information in an administrative file is collected under existing regulations in parts 312 (OMB control number 0910–0014), 314 (OMB control number 0910–0001), and part 601 (21 CFR part 601) (OMB control number 0910–0315), which specify the information that manufacturers must submit so that FDA may properly evaluate the safety and effectiveness of drugs and biological products. This information is usually submitted as part of an IND, NDA, or biologics license application (BLA), or as a supplement to an approved application. While FDA already possesses in the administrative file the information that would form the basis of a decision on a matter in dispute resolution, the submission of particular information regarding the request itself and the data and information relied on by the requestor in the appeal would facilitate timely resolution of the dispute. The guidance describes the following collection of information not expressly specified under existing regulations: The submission of the request for dispute resolution as an amendment to the application for the underlying product, including the submission of supporting information with the request for dispute resolution.

FDA's regulations (§§ 312.23(d), 314.50, 314.94, and 601.2) state that information provided to the agency as part of an IND, NDA, ANDA, or BLA is to be submitted in triplicate and with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs, ANDAs, and BLAs. Both forms have valid OMB control numbers as follows: FDA Form 1571, OMB control number 0910–0014, expires November 30, 2002; and FDA Form 356h, OMB control number 0910–0001, expires March 31, 2005. In the guidance document, CDER and CBER ask that a request for formal dispute resolution be submitted as an amendment to the application for the underlying product and that it be submitted to the agency in triplicate with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The agency recommends that a request be submitted as an amendment in this manner for the following two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the agency's tracking databases enables the appropriate agency official to monitor progress on the resolution of the dispute and to ensure that appropriate steps will be taken in a timely manner.

CDER and CBER have determined and the guidance recommends that the following information should be submitted to the appropriate center with each request for dispute resolution so that the center may quickly and efficiently respond to the request: (1) A brief but comprehensive statement of each issue to be resolved, including a description of the issue, the nature of the issue (i.e., scientific, procedural, or both), possible solutions based on information in the administrative file, whether informal dispute resolution was sought prior to the formal appeal, whether advisory committee review is sought, and the expected outcome; (2) a statement identifying the review division/office that issued the original decision on the matter and, if applicable, the last agency official that attempted to formally resolve the matter; (3) a list of documents in the administrative file, or additional copies of such documents, that are deemed necessary for resolution of the issue(s); and (4) a statement that the previous supervisory level has already had the opportunity to review all of the material relied on for dispute resolution. The information that the agency suggests submitting with a formal request for dispute resolution consists of: (1) Statements describing the issue from the perspective of the person with a dispute, (2) brief statements describing the history of the matter, and (3) the documents previously submitted to FDA under an OMB approved collection of information.

Based on FDA's experience with dispute resolution, the agency expects that most persons seeking formal dispute resolution will have gathered the materials listed previously when identifying the existence of a dispute with the agency. Consequently, FDA anticipates that the collection of information attributed solely to the guidance will be minimal.

*Description of Respondents*: A sponsor, applicant, or manufacturer of a drug or biological product regulated by the agency under the act or section 351 of the Public Health Service Act who requests formal resolution of a scientific or procedural dispute.

*Burden Estimate*: Provided below is an estimate of the annual reporting burden for requests for dispute resolution. Based on data collected from review divisions and offices within CDER and CBER, FDA estimates that approximately seven sponsors and applicants (respondents) submit requests for formal dispute resolution to CDER annually and approximately one respondent submits requests for formal dispute resolution to CBER annually. The total annual responses are the total number of requests submitted to CDER and CBER in 1 year, including requests for dispute resolution that a single respondent submits more than one time. FDA estimates that CDER receives approximately 10 requests annually and CBER receives approximately 1 request annually. The hours per response is the estimated number of hours that a respondent would spend preparing the information to be submitted with a request for formal dispute resolution in accordance with this guidance, including the time it takes to gather and copy brief statements describing the issue from the perspective of the person with the dispute, brief statements describing the history of the matter, and supporting information that has already been submitted to the agency. Based on experience, FDA estimates that approximately 8 hours on average would be needed per response. Therefore, FDA estimates that 96 hours will be spent per year by respondents requesting formal dispute resolution under the guidance.

In the **Federal Register** of July 18, 2002 (67 FR 47385), the agency requested comments on the proposed collections of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Request for Formal Dispute Resolution | No. of Respondents | No. of Respondents per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| CDER | 7 | 1.4 | 10 | 8 | 80 |
| CBER | 1 | 2 | 2 | 8 | 16 |
| Total | | | | | 96 |

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

Dated: October 9, 2002.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 02–26326 Filed 10–15–02; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 02N–0284]**

### Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling: Health Claims; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by November 15, 2002.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**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.

### Food Labeling: Health Claims; Record Retention Requirements for the Soy Protein and Risk of Coronary Heart Disease Health Claim—21 CFR 101.82(c)(2)(ii)(B) (OMB Control Number 0910–0428)—Extension

This regulation authorizes a health claim for food labels about soy protein and coronary heart disease (CHD). Section 403(r)(3)(A)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(3)(A)(i)) provides for the use of food label statements characterizing a relationship of any nutrient of the type required to be in the label or labeling of the food to a disease or a health related condition only where that statement meets the requirements of the regulations issued by the Secretary of Health and Human Services to authorize the use of such a health claim. To bear the soy protein and CHD health claim, foods must contain at least 6.25-gram soy protein per reference amount customarily consumed. Analytical methods for measuring total protein can be used to quantify the amount of soy protein in foods that contain soy as the sole source of protein. At the present time, there is no validated analytical methodology available to quantify the amount of soy protein in foods that contain other sources of protein. For these latter foods, FDA must rely on information known only to the manufacturer to assess compliance with the qualifying amount of soy protein. Thus, FDA requires manufacturers to have and keep records to substantiate the amount of soy protein in a food that bears the health claim and contains sources of protein other than soy, and to make such records available to appropriate regulatory officials upon written request. The information collected includes nutrient databases or analyses, recipes or formulations, purchase orders for ingredients, or any other information that reasonably substantiates the ratio of soy protein to total protein.

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