IV. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

V. Electronic Access

In order to receive ''Guidance on the Recognition and Use of Consensus Standards'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes this guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 007'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*. You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable data base for ''FDA Recognized Consensus Standards,'' through hyperlinks at *http://www.fda.gov/cdrh/stdsprog.html*. This **Federal Register** notice of modifications in FDA's recognition of consensus standards will be available, upon publication, at *http://www.fda.gov/cdrh/fedregin.html*.

VI. Submission of Comments

You may, at any time, submit to the contact person (*see* **FOR FURTHER INFORMATION CONTACT**) written comments regarding this document. You should submit two copies of any comments, except that individuals may submit one copy. You must identify comments with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of ''Modifications to the List of Recognized Standards, Recognition List Number: 007.''

Dated: September 18, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–24954 Filed 10–1–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0389]

Draft Guidance for Industry on Nonclinical Studies for Development of Pharmaceutical Excipients; 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 Studies for Development of Pharmaceutical Excipients.'' The draft guidance document provides guidance concerning development of safety profiles to support use of new excipients as components of drug or biological products. It is intended for use by reviewers within both the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) and by interested individuals in industry. The goals of this document are to foster and expedite the development of new excipients, communicate to industry current CDER and CBER thoughts pertaining to safety data needed to support excipient development, and increase uniformity within CDER and CBER on expectations for the nonclinical development of excipients.

DATES: Submit written or electronic comments on the draft guidance by December 31, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this 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 Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER-FAX or 301–827–3844. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Robert E. Osterberg, Center for Drug Evaluation and Research (HFD–024), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5482, or Martin D. Green, Center for Biologics Evaluation and Research (HFM–579), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–5349.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Nonclinical Studies for Development of Pharmaceutical Excipients.'' Excipients are potential toxicants. It is important to perform risk-benefit assessments on excipients for use in drug products and to establish permissible limits for these compounds. These activities necessitate the availability of safety data. Consequently, there is a perception that development of new excipients is resource intensive. With proper planning, however, it is often possible to assess the toxicology of an excipient in a relatively efficient manner. Moreover, CDER and CBER recognize that existing human data for some excipients may substitute for nonclinical safety data, and use in previously approved products or GRAS status as a food additive will continue to receive consideration. This draft

guidance describes the nonclinical data that should be generated to support the safety of an inactive ingredient in the amounts administered if adequate, relevant prior human use cannot be documented.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on nonclinical studies for development of pharmaceutical excipients. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: September 23, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–24985 Filed 10–1–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Submission for OMB review; comment request; The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer

SUMMARY: Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 20, 2001, page 33103–4 and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB number.

Proposed Collection

Title: The Sister Study: Environmental and Genetic Risk Factors for Breast Cancer. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* We will study environmental and genetic risk factors for the development of breast cancer in a cohort of sisters of women who have had breast cancer. In the United States, approximately 192,000 new cases were diagnosed in 2001, accounting for 30% of all new cancer cases among women. The etiology of breast cancer in complex, with both genetic and environmental factors likely playing a role. Environmental risk factors, however, have been difficult to identify. Sisters of women with breast cancer have nearly twice the risk of developing breast cancer themselves. By focusing on a susceptible population, more precise estimates of the contribution of environmental and other non-genetic factors to disease risk may be possible.The increased risk of cancer, and the expected higher prevalence of both relevant genes and exposures (both shared with their sister who had breast cancer) will facilitate the study of gene-environment interactions. Once assembled, the cohort will be useful for studying other diseases in women. We will enroll a cohort of 50,000 women who have not had breast cancer over a 4-year period, with 37,500 enrolled during the first 3 years of the study. These breast cancer-free sisters will be followed annually for the development of breast cancer and other diseases. We expect 300 cases of breast cancer per year (on average) to develop in a cohort of 50,000 women. In addition, we will enroll and follow 1,500 of the index sisters (1125 during the first 3 years) whose breast cancer diagnosis was within four months prior to enrollment. These ''index'' cases will allow comparison of case-control pairs of sisters and prospective study of the impact of environmental exposures and genes on prognosis.

Frequency of Response: On occasion. For those who qualify and enroll: one initial 15-minute screening contact [telephone or internet, one 2-hour telephone interview, one mailed self-administered questionnaire (1.5 hours), biological and environmental specimen collection (1 hours), and annual follow-up questionnaires (0.5 hours). for those who don't enroll: one 15-minute screening contact (internet or phone). For women with breast cancer or who develop breast cancer during follow-up: validation of diagnosis through doctor's office. *Affected Pubic:* Individuals or households, doctor's office. *Types of Respondents:* Unaffected sisters of women diagnosed with breast cancer, aged 35–74, from all socioeconomic backgrounds and ethnicities and women with recently diagnosed breast cancer. The annual reporting burden in as follows: *Estimated Number of Respondents:* 151,800–50,000 study respondents per year, of whom 12,875 will qualify and enroll—including 12,500 unaffected women plus 500 index cases of incident breast cancer. (**Note:** Total cohort enrollment of 50,000 cancer-free sisters and 1,500 index cases of incident breast cancer will take 4 years to achieve, requiring an estimated 2000, 000 respondents in all.) In addition, there will be a total of 1,575 doctor office respondents to validate diagnoses. The first year cost per women who enrolls in the study is estimated to be $95 (based on 4.75 hours of $20 hourly wage). Cost equivalent per follow-up year for enrolled women is $10. Total cost to women who don't enroll is $5. Cost to doctor's offices is $10 (assuming $40 per hour). *Estimated Number of Responses per Respondent See* table below. *Average Burden Hours Per Response: See* table below. *Estimated Total Burden Hours Requested:* 231,240 over 3 years (see table). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

BILLING CODE 4140–01–M