The 1984 amendments included what is now section 505(j)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(6)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

Ibuprofen (Midol®) 200-mg capsule is the subject of approved ANDA's 70–626 and 71–002. On September 7, 1987, Sterling Winthrop, Inc., (Winthrop) obtained approval to market the ibuprofen 200-mg capsule. Winthrop never in fact marketed this drug product. The right to market the Midol® 200-mg capsule was subsequently transferred to Bayer Corp., which never marketed the drug product and has indicated that it has no plans to market it in the future.

On June 27, 1996, Private Formulations, Inc., submitted a citizen petition (Docket No. 96P–0212/CP1) under 21 CFR 10.30 to FDA requesting that the agency determine whether ibuprofen 200-mg capsule was withdrawn from sale for reasons of safety or effectiveness. FDA has determined that, for purposes of §§ 314.161 and 314.162(c), never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its records and under §§ 314.161 and 314.162(c) has determined that the ibuprofen 200-mg capsule was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will maintain ibuprofen 200-mg capsule in the ''Discontinued Drug Product List'' contained in the ''Approved Drug Products with Therapeutic Equivalence Evaluations.'' The ''Discontinued Drug Product List'' lists, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDA's that refer to ibuprofen 200-mg capsule may be approved by the agency.

Dated: November 7, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–29238 Filed 11–14–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0391]

Review of Infant Formula Nutrient Requirements for Preterm Infants; Announcement of Study; Request for Scientific Data and Information; Announcement of Open Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) is about to undertake an assessment of the energy and macronutrient levels in infant formulas intended for preterm infants who are of low birth-weight because of their premature birth. The agency has requested that LSRO/FASEB provide an up-to-date scientifically documented report based on its assessment. FDA intends to consider this report and other relevant information in deciding whether a modification of the levels of energy and macronutrients listed in the FDA regulation for term infant formulas is necessary for formulas intended to meet the special needs of preterm infants. To assist in the preparation of its scientific report, LSRO/FASEB is inviting the submission of scientific data and information bearing on this topic. LSRO/FASEB will also provide an opportunity for oral presentations at an open meeting.

DATES: LSRO expects to hold an open meeting on this topic during the period January 2, 1997, to March 31, 1997. FDA and LSRO will announce the date of the meeting as soon as it is set. Requests to make oral presentations must be submitted in writing by December 23, 1996. Written presentations of scientific data, information, and views should be submitted on or before the date of the open meeting.

ADDRESSES: The open meeting will be held in the Chen Auditorium, Lee Bldg., Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD. Written requests to make oral presentations of scientific data, information, and views at the open meeting should be submitted to Daniel J. Raiten (address below) and to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of the scientific data, information, and views are to be submitted to each office. These two copies are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel J. Raiten, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814–3998, 301–530–7030, or Linda H. Tonucci, Center for Food Safety and Applied Nutrition (HFS–456), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5372.

SUPPLEMENTARY INFORMATION: FDA has a contract (223–92–2185) with FASEB concerning the analysis of scientific issues that bear on the safety of foods and cosmetics. The objectives of this contract are to provide information to FDA on general and specific issues of scientific fact associated with the analysis of human nutrition.

Formulas for infants with low birth-weight are currently regulated as exempt infant formulas under the Federal Food, Drug, and Cosmetic Act (the act). Exempt infant formulas may have nutrients or nutrient levels that are different from those that are codified in 21 CFR 107.100, if the manufacturer of the infant formula can justify the nutrient deviation. LSRO will perform a review to consider the scientific basis for providing different recommendations for energy and macronutrients (protein, fat, including long-chain polyunsaturated fatty acids (LCPUFA's), and carbohydrates) in formulas for low birth-weight preterm infants.

FDA is announcing that it has asked FASEB, as a task under contract 223–92–2185, to provide FDA's Center for Food Safety and Applied Nutrition with an up-to-date review of the nutrient requirements of preterm infants and the resultant effects of new information about nutritional needs on recommendations for levels of nutrients in formulas for preterm infants. In response to this request, FASEB has directed LSRO to obtain state-of-the-art, scientific information on infant nutrient requirements and related scientific questions on specifications for preterm infant formula. The LSRO/FASEB will undertake a study and prepare a documented scientific report that summarizes the available information related to these questions.

LSRO, in consultation with expert scientists and professional organizations

involved in the field of infant nutrition (e.g., American Academy of Pediatrics (AAP), the Food and Nutrition Board (FNB) of the National Academy of Sciences), will perform a review of the scientific and medical literature with a particular emphasis on studies published since 1986, when Congress last amended the infant formula provisions of the act. Requirements of other governmental bodies will also be considered in this review. Specifically, LSRO will address the following issues:

(1) What scientific basis is there to support requirements for energy and macronutrients (protein, fat, and carbohydrate) in infant formulas intended for use by preterm infants as distinct from the requirements for energy and macronutrients in formulas for term infants? The American Academy of Pediatrics, the European Society for Pediatric Gastroenterology and Nutrition, and the Canadian Pediatric Society have proposed some nutrient requirements for preterm infants distinct from those for term infants. Has scientific knowledge advanced to the point that distinct composition standards for energy and macronutrients in formulas for these preterm infants are warranted?

(2) Nutrient requirements of hospitalized preterm infants who are fed enteral formulas are sometimes described according to stages such as a first or transition stage (between birth and 10 days of age), a stable growing stage (from about 10 days until discharge from hospital, 6 to 8 weeks after birth), and a post-discharge stage (from discharge home to approximately 1 year of age). Is there scientific evidence to justify more than one set of energy and macronutrient requirements to support growth and development of the hospitalized preterm infant at the different stages of development? If so, how should the stages be defined? Are the energy and macronutrient requirements for infant formulas for term infants sufficient for healthy post-discharge preterm infants? Is there scientific evidence to support specific deviations from current nutrient standards for healthy post-discharge preterm infants and if so, what would they be and to what stage (age/weight) should these special formulas be given?

(3) Does available evidence establish the essentiality of addition of subcomponents of the macronutrients (specifically, taurine, carnitine, and LCPUFA's) to formulas for preterm infants, and if so, does the evidence establish what the amount and ratios of these compounds should be in the formula? For example, the Canadian ''Guidelines for the Composition and Clinical Testing for Formulas for Preterm Infants'' (p. 17) finds that term infant formulas containing adequate and balanced 18:2n-6 and 18:3n-3 fatty acids do not require addition of the 20 and 22 carbon n-6 and n-3 fatty acids. Is there evidence to suggest that this finding has application to preterm infant formulas? If so, is there an optimum level and ratio of 18:2n-6 and 18:3n-3 fatty acids in formulas for preterm infants?

Does the available evidence address the issue of safety of various sources of these LCPUFA's for use in preterm infant formulas? If so, is there a safe source of LCPUFA's?

(4) Does available evidence establish the essentiality of addition of nucleotides to formulas for preterm infants, and if so, does the evidence establish what the amounts should be in the formulas?

LSRO will use these questions as a guide in its research and in the drafting of its report. LSRO notes that the recommendations derived from the answers to the above questions will be made in consultation with liaisons from the American Academy of Pediatrics' Committee on Nutrition and the Institute of Medicine's Food and Nutrition Board. A comprehensive final report that documents and summarizes the results of the evaluation will be prepared.

FDA and FASEB are announcing that the LSRO/FASEB expects to hold an open meeting on this topic during the period January 2, 1997 to March 31, 1997. FDA and FASEB will announce the date of the meeting as soon as it is set. The open meeting will be held in the Chen Auditorium, Lee Bldg., FASEB (address above). FASEB anticipates that the open meeting will last 1 day, depending on the number of requests to make oral presentations. Requests to make oral presentations at the open meeting must be submitted in writing by December 23, 1996. Written requests to make oral presentations of scientific data, information, and views at the open meeting should be submitted to Daniel J. Raiten (address above) and to the Dockets Management Branch (address above). Two copies of the material to be presented must be submitted to each office on or before the date of the open meeting.

FDA and FASEB are also inviting submission of written presentations of scientific data, information, and views. These materials should be submitted on or before the date of the open meeting. Two copies of the written materials must be submitted to each office.

Under its contract with FDA, FASEB will provide the agency with a scientific report on or about September 30, 1997.

Dated: November 5, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–29303 Filed 11–14–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[HCFA–8003]

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposals for the collection of information. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Request:* Extension, without change, of a previously approved collection for which approval has expired; *Title of Information Collection:* Home and Community-Based Services Waiver Requests; *Form No.:* HCFA–8003; *Use:* Under a Secretarial waiver, States may offer a wide array of home and community-based services to individuals who would otherwise require institutionalization. States requesting a waiver must provide certain assurances, documentation and cost & utilization estimates which are reviewed, approved and maintained for the purpose of identifying/verifying States' compliance with such statutory and regulatory requirements; *Frequency:* Other—When a State requests a waiver or amendment to a waiver; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 50; *Total Annual Responses:* 140; *Total Annual Hours:* 8,200.

To request copies of the proposed paperwork collection referenced above, E-mail your request, including your address, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410)