Intracorneal
Intracoronary
Intradermal
Intradiscal (intraspinal)
Intrahepatic
Intralesional
Intralymphatic
Intramedullar (bone marrow)
Intrameningeal
Intramuscular
Intraocular
Intrapericardial
Intraperitoneal
Intrapleural
Intrasynovial
Intratumor
Intrathecal
Intrathoracic
Intratracheal
Intravenous bolus
Intravenous drip
Intravenous (not otherwise specified)
Intravesical
Iontophoresis
Nasal
Occlusive dressing technique
Ophthalmic
Oral
Oropharyngeal
Other
Parenteral
Periarticular
Perineural
Rectal
Respiratory (inhalation)
Retrobulbar
Subconjunctival
Subcutaneous
Subdermal
Sublingual
Topical
Transdermal
Transmammary
Transplacental
Unknown
Urethral
Vaginal

Dated: January 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–959 Filed 1-14-98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0391]

Micronutrient Requirements for Preterm Infant Formulas; 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 American Society of Nutritional Sciences (ASNS) is undertaking an assessment of the scientific basis for the need to establish specific recommendations (minimum and maximum levels) for intake by preterm infants of micronutrients, that is, the vitamins and minerals specified in the Federal Food, Drug, and Cosmetic Act (the act) and selenium, molybdenum, chromium, and fluoride. To assist in this task, LSRO/ASNS is inviting the submission of scientific data and information on this topic and will provide an opportunity for oral presentations at an open meeting.

DATES: The LSRO will hold a 1-day public meeting on this topic on Friday, March 27, 1998. The meeting will begin at 9 a.m. Requests to make oral presentations at the open meeting must be submitted in writing and received by Friday, February 13, 1998. Hard copies of oral presentations should be delivered by Friday, March 20, 1998. Individuals may submit, in writing, scientific data, information, and views by July 1, 1998.

ADDRESSES: The open meeting will be held in the Chen Auditorium, Lee Bldg., American Society of Nutritional Sciences, 9650 Rockville Pike, Bethesda, MD. Written requests to make oral presentations of scientific data, information, and views at the open meeting should be submitted both 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 should 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 ASNS 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.

Infant formulas for use by infants with low birth-weight are subject to regulation under 412(h) of the act (21 U.S.C. 350a(h)). Exempt infant formulas are permitted to 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. The agency believes that some deviations from the nutrient requirements established for term infants may be appropriate to promote healthy growth and development in low birth-weight preterm infants. These deviations have yet to be defined. Consequently, FDA has asked ASNS to perform a review to consider whether there is a scientific basis for having different recommendations for micronutrients in formulas for low birth-weight preterm infants.

FDA is announcing that it has asked ASNS, 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 low birth-weight preterm infants, including a review of the implications of these requirements on the need for recommendations for levels of nutrients in formulas for these infants. In response to this request, ASNS has directed its LSRO to obtain state-of-the-art scientific information on low birth-weight preterm infant nutrient requirements and related scientific questions on specifications for preterm infant formula. The LSRO/ASNS will undertake a study and prepare a documented scientific report that summarizes the available information related to these issues.

LSRO/ASNS will perform an assessment of the nutrient requirements for infant formulas intended for use by preterm (low birth-weight) infants that addresses the following issues:

(1) What scientific basis is there to specify requirements for micronutrients in infant formulas intended for use by low birth-weight preterm infants? The American Academy of Pediatrics, the European Society for Pediatric Gastroenterology and Nutrition, and the Canadian Pediatric Society have proposed nutrient requirements for low birth-weight infants distinct from those for term infants. Has scientific knowledge advanced to the point to warrant distinct micronutrient composition standards for formulas for low birth-weight preterm infants?

(2) Micronutrient requirements of preterm infants fed enteral formulas are sometimes described according to a first or transition stage (between birth and 10 days of age), a stable growing stage (from about 10 days until discharge

from the hospital, often 6 to 8 weeks after birth), and a postdischarge stage (from discharge home to approximately 1 year). Is there scientific evidence to support more than one set of micronutrient requirements for infant formulas to support healthy growth and development of the preterm infant at the different stages of development? Are the micronutrient requirements for term infant formulas sufficient for thriving postdischarge preterm infants?

(3) What is the scientific evidence to support a dietary recommendation for a minimum and a maximum quantitative nutrient concentration for selenium, chromium, molybdenum, and fluoride in preterm infant formulas? What limits of intake would ensure safe and adequate exposure to these nutrients? Is there a need to specify the chemical form or other characteristics of these nutrients or their sources to ensure safety and adequacy?

(4) Certain micronutrient interactions, such as vitamin E:linoleic acid, vitamin B6:protein, and calcium:phosphorus, have been identified for full-term infants which have helped to ensure the adequacy of full-term formulas. Are there micronutrient interactions that can be identified for preterm infants that will help to ensure the nutrient adequacy of infant formulas for this population? Are there recommended ratios for metal cations? Is the evidence of interaction between these minerals sufficiently strong to suggest that the ratios should be ensured for the health of preterm infants?

(5) In an earlier task under this contract (61 FR 58566, November 15, 1996), LSRO/ASNS agreed to investigate whether there is evidence of a benefit to preterm infants from ingestion of taurine and carnitine, as well as whether there is evidence that would provide a basis for a requirement for minimal intakes of each of these substances. Is there adequate evidence of benefit of other substances not listed in this notice to support a requirement for their inclusion in preterm infant formulas?

LSRO/ASNS will use these questions as a guide in its investigation. ASNS will prepare a comprehensive final report that documents and summarizes the results of its evaluation.

FDA and ASNS are announcing that the LSRO/ASNS expects to hold a public meeting on this topic on Friday, March 27, 1998. The meeting will begin at 9 a.m. It is anticipated that the public meeting will be up to 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 and received by Friday, February 13, 1998. Written requests to make oral presentations of scientific data, information, and views at the open meeting should be submitted both 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 March 20, 1998. The open meeting will be held in the Chen Auditorium, Lee Bldg., ASNS (address above).

FDA and ASNS are also inviting submission of written presentations of scientific data, information, and views. These materials should be submitted on or before July 1, 1998. Two copies of the written materials must be submitted to each office.

In accordance with its contract with FDA, ASNS will provide the agency with a scientific report on or about September 30, 1998.

Dated: January 6, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–958 Filed 1–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–9044]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Health Care Financing Administration.

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, is publishing the following summary of proposed collections for public comment. 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.

Type of Information Collection Request: Extension of a currently approved collection; *Title of Information Collection:* Provider Reimbursement Manual, Part 1—Chapter 27, Section 2721, 2722 and 2725, Request for Exception to ESRD Composite Rates and Supporting Regulations in 42 CFR 413.170; *Form No.:* HCFA–9044 (OMB# 0938–0296); *Use:* Sections 2721, 2722 and 2525 of the Provider Reimbursement Manual describe the information ESRD facilities must submit in justifying an exception request to their composite rate for outpatient dialysis services.; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions and Federal Government; *Number of Respondents:* 275; *Total Annual Responses:* 275; *Total Annual Hours:* 13,200.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: January 7, 1998.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Information Technology Investment Management Group, Division of HCFA Enterprise Standards.

[FR Doc. 98–1064 Filed 1–14–98; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Endangered and Threatened Species Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications.

The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of