The total cost to respondents is estimated at $450,000.

Dated: February 28, 1996.

Wilma G. Johnson,

Acting Associate Director for Policy Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 96–5023 Filed 3–4–96; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0005]

Review of Infant Formula Nutrient Requirements; 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 begin a review of data on the nutritional needs of infants and to make recommendations on appropriate concentrations of nutrients in formulas for term infants. The Infant Formula Act of 1980 directed FDA to ensure the safety and nutritional quality of infant formulas. Nutrient specifications for infant formulas are codified under the regulations for food and human consumption that were most recently revised in 1985. This review by LSRO/FASEB was requested by the agency, and it is is intended to provide FDA with an up-to-date review of the nutritional needs of infants and of how those needs should be reflected in the levels of nutrients in formulas for term infants. To assist in the preparation of its scientific report, LSRO/FASEB is inviting the submission of scientific data and information on this topic. In addition, LSRO/FASEB 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 May 31, 1996. 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 May 10, 1996. Written presentations of scientific data, information, and views should be submitted on or before May 31, 1996.

ADDRESSES: Submit written requests to make oral presentations of scientific data, information, and views at the open meeting to Sue Ann Anderson, Life Sciences Research Office, Federation of American Societies for Experimental Biology, 9650 Rockville Pike, Bethesda, MD 20814, 301–530–7030, 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.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Yetley, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

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.

The Infant Formula Act of 1980 (Pub. L. 96–359) directed that FDA ensure the safety and nutritional quality of infant formulas. Regulations for infant formulas are codified in part 107 (21 CFR part 107) and include nutrient specifications for these products (§ 107.100). These nutrient specifications were last revised in 1985. In 1986, the infant formula provisions of the Federal Food, Drug, and Cosmetic Act (the act) were amended (Pub. L. 99–570). Among the changes that Congress made was to add the list of specifications to section 412(i)(1) of the act (21 U.S.C. 350a(i)(1)). The act also provides that the Secretary of Health and Human Services (and by delegation FDA) can revise this list by regulation (section 412(i)(2) of the act).

Since 1985, new data on nutritional needs of infants have accumulated from scientific investigations. In addition, a recommended dietary allowance (RDA) was set for selenium and estimated safe and adequate daily dietary intakes (ESADDI) were recommended for fluoride, chromium, and molybdenum by the National Research Council in 1989 (see Ref. 1). These four minerals are not included in the nutrient specifications for infant formulas in section 412(i) of the act or § 107.100.

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 nutritional needs of infants and of the resultant effects of new information about nutritional needs of infants on recommendations for levels of nutrients in formulas for term infants. In response to this request, FASEB has directed its Life Sciences Research Office to obtain state-of-the-art scientific information on infant nutritional needs and related scientific questions on infant formula specifications. The LSRO/FASEB will undertake a study and prepare a documented scientific report that summarizes the available information related to these questions. LSRO has advised FDA that in preparing this report, it will consult with academic and medical experts and professional organizations concerned with nutritional needs of infants.

The objectives of this report will include evaluations of the following types of information: (1) New findings on nutrient requirements of infants and on any resultant need to establish or revise minimum and maximum amounts of nutrients required in formulas for term infants; (2) for macronutrients, evidence to support the addition of specific proteins (e.g., lactoferrin), carbohydrates (e.g., lactose), or fats (e.g., omega-3 fatty acids) to infant formulas; (3) information on the dietary essentiality of certain minerals (selenium, chromium, molybdenum, and fluoride), whether they should be included in infant formulas and, if so, at what levels; (4) scientific information on effects of ingestion of nucleotides, taurine, carnitine, urea, cholesterol, glutathione, and oligosaccharides; (5) information on differences in nutrient requirements of older infants (4 months of age and older) compared to infants younger than 4 months; (6) factors affecting nutrient stability and the product shelf life of infant formulas; and (7) the scientific basis for use of methods other than the protein efficiency ratio (PER) to ensure the quality of proteins used in infant formulas. A comprehensive final report that documents and summarizes the results of the evaluation will be prepared.

FDA and FASEB are announcing that LSRO/FASEB will hold a public meeting on this topic on May 31, 1996. The meeting will begin at 9 a.m. It is anticipated that the public meeting will be held for 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 May 10, 1996. Written requests to make oral presentations of scientific data, information, and views at the open meeting should be submitted to LSRO/FASEB (address above) and to the Dockets Management Branch (HFA–305), Food and Drug Administration (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 LSRO/FASEB are also inviting submission of written presentations of scientific data, information, and views. These materials should be submitted on or before May 31, 1996. Two copies of the written materials must be submitted to both offices.

Under its contract with FDA, FASEB will provide the agency with a scientific report on or about March 31, 1997.

Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. National Research Council, ''Recommended Dietary Allowances,'' 10th ed., Washington, DC, National Academy Press, 1989.

Dated: February 27, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–5117 Filed 3–4–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

Notice of Hearing: Reconsideration of Disapproval of Pennsylvania State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on April 10, 1996; 10:00 a.m. in Room 5020; 3535 Market Street, Philadelphia, Pennsylvania to reconsider our decision to disapprove Pennsylvania SPA 94–17.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by March 20, 1996.

FOR FURTHER INFORMATION CONTACT: Stan Katz, Presiding Officer, HCFA, C1–04–27, 7500 Security Boulevard, Baltimore, Maryland 21224–1850, Telephone: (410) 786–2661.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to disapprove Pennsylvania State plan amendment (SPA) number 94–17.

Section 1116 of the Social Security Act (the Act) and 42 CFR, Part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. The Health Care Financing Administration (HCFA) is required to publish a copy of the notice to a State Medicaid agency that informs the agency of the time and place of the hearing and the issues to be considered. If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.

Any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

Pennsylvania submitted SPA 94–17 for approval on December 29, 1995. The issues involved in this reconsideration are as follows: (1) The revised supplement submitted with SPA 94–17 provides for DSH payments to county nursing facilities prior to the proposed effective date of the plan amendment in violation of federal law at 42 CFR 447.256(c); (2) federal appropriations law, as interpreted by HCFA prohibit the ''retroactive payment adjustments'' which would be authorized under SPA 94–17; (3) the Department failed to publish adequate public notice in advance of the alleged change in its payment methods in accordance with the requirements at 42 CFR 447.205(c); and (4) the Department did not submit adequate information in support of its Medicare upper limit assurance at 42 CFR 447.272 and 447.253(b)(2).

In this plan amendment, the State of Pennsylvania revises significantly the State's nursing facility payment plan methodology to provide the formula for calculating a ''disproportionate share'' payment to county nursing facilities for State fiscal years (SFYs) 1993, 1994, and 1995.

These ''disproportionate share'' payments to county nursing facilities began in SFY 1991 and were continued in SFY 1992 under an approved State plan amendment. The State has revised significantly its nursing facility payment methodology three times since then (SFYs 1993, 1994 and 1995), but did not amend the State plan concerning these payments before the payments were made. Since Pennsylvania sought approval of a payment adjustment that was earlier than permissible under long-standing regulatory provisions governing effective dates for plan amendments, HCFA disapproved the amendment.

Issue Regarding Effective Date of Payment Adjustments

Federal regulations at 42 CFR 447.256 specify that an approved state plan amendment becomes effective not earlier than the first day of the calendar quarter in which an approvable amendment is submitted. This amendment was submitted on December 29, 1994. Consequently, the *earliest* date for which Federal financial participation would be available for ''disproportionate share'' payments made under this amendment, if approved, was October 1, 1994. Even though this is the proposed effective date for SPA 94–17 requested by the State, this amendment could not be approved, as it would provide for retroactive ''disproportionate share'' payments for periods prior to the proposed effective date.

Pennsylvania's retroactive payment adjustments are also prohibited by the Department's appropriations law. The appropriations law provides that Medicaid payments may be made for any quarter with respect to state plan amendments which are in effect in that quarter, and which were submitted in, or prior to, that quarter and approved in that, or any later quarter. HCFA has interpreted this to mean that there can be no retroactive payments for any plan amendment which could result in an increase in Medicaid payments. If approved, this amendment would have increased Medicaid payments in quarters prior to the quarter in which the amendment was submitted; therefore, HCFA had no choice but to disapprove this SPA.

Issue Regarding Public Notice

Federal regulations provide that public notice of any significant proposed change in methods or standards for setting payment rates must be published before the proposed effective date of the change. Pennsylvania requested an effective date of October 1, 1994. However, the notice published on July 31, 1993, and relied on by the State to support the revised ''disproportionate share'' payments for SFY 1995, was defective. Even though the July 31, 1993, notice appears to be adequate for the SFY 1994 revised payment methodology, it is not sufficient for the SFY 1995 payment methodology because it did not contain an estimate of the expected increases in annual expenditures for SFY 1995, as required by Federal rules. Pennsylvania did not submit a plan amendment for