2. The State Champion Award

This award is granted to three schools in each state which qualify the highest percentage of eligible students for the Presidential Physical Fitness Award. Schools receive a certificate of recognition, and each student in the school who received the Presidential Physical Fitness Award receives a State Champion emblem.

3. The National Physical Fitness Demonstration Centers

This award focuses attention on individual schools, recognized by State Departments of Education, which have outstanding programs of physical education that contribute to students' physical fitness. Each Demonstration Center receives a certificate and a pennant distributed by the State Director. Organizations (schools, youth and community groups, etc.) which participate in the PCPFS awards programs purchase the award and recognition materials directly from the administering organization.

The organization selected shall furnish the necessary personnel, materials, services and facilities to administer this PCPFS program (awards, recognitions and activities), including the purchase and/or production of all award materials; distribution of award materials; promotion; statistical evaluations of programs; quarterly and annual budget and demographic reports; and other administrative duties. These duties will be determined in a Memorandum of Agreement and an annual plan. The organization will be expected to provide input regarding new activities or initiatives to support the program, and recommend methods to improve program usage and promotion. The organization also will work with the PCPFS to consider other recognitions/programs bearing the President's Council on Physical Fitness and Sports and/or Presidential insignias.

An organization interested in administering the programs should submit pertinent information regarding its qualifications for evaluation purposes on each of the following areas: (1) Experience in administering national awards programs; (2) Discussion of specific work previously performed or currently being performed, with particular emphasis on those national projects dealing with physical fitness, sports or other physical activities of a similar nature, with schools and organizations; (3) Personnel: name, professional qualifications and specific experience of key personnel who would be available to work on these projects; (4) Facilities: availability and description of facilities required to administer the program as well as computer based telecommunication resources; (5) Financial Management: discussion of experience in developing an annual budget and collecting and managing monies from organizations or individuals; (6) Proposed plan for managing the President's Council on Physical Fitness and Sports awards programs, including such financial aspects as cost of award materials, promotion, distribution and program management. The organization will be selected by the PCPFS based on its qualifications and capability to administer a program of this nature.

Dated: November 12, 1996.

Sandra Perlmutter,

Executive Director, President's Council on Physical Fitness and Sports.

[FR Doc. 96–29287 Filed 11–14–96; 8:45 am]

BILLING CODE 4160–17–M

Centers for Disease Control and Prevention

ICD–9–CM Coordination and Maintenance Committee Meeting

The National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), announces the following meeting.

Name: ICD–9–CM Coordination and Maintenance Committee (C&M).

Times and Dates: 10 a.m.-Open, December 5, 1996; 8:30 a.m.-3:30 p.m., December 6, 1996.

Place: Auditorium, Health Care Financing Administration Building, 7500 Security Boulevard, Baltimore, Maryland 21244.

Status: Open.

Purpose: The ICD–9–CM Coordination and Maintenance Committee will be holding its final meeting of the year. This meeting is a public forum for the presentation of proposed modifications to the International Classification of Diseases, ninth-revision, clinical modification. Topics to be discussed include Crohn's disease, obstetric chapter modifications, febrile convulsions, external cause modifications, hepatitis carrier, high-risk screening mammogram, update on ICD–10 Procedure Coding System, partial ventribulectomy, thalamic stimulation for tremors, arthroplasty with cement spacers, and addenda.

Agenda items are subject to change as priorities dictate.

Notice: In the interest of security, the Department of Health and Human Services has instituted stringent procedures for entrance into the building by non-government employees. Thus, persons without a government identification card will need to show photo identification and sign-in.

Contact Persons for More Information: Substantive program information may be obtained from Amy Gruber, Health Care Financing Administration, 7500 Security Boulevard, Room C5–06–27, Baltimore, Maryland 21244, telephone 410/786–1542, or Donna Pickett, Co-chair, ICD–9–CM Coordination and Maintenance Committee, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436–7050, extension 142.

Dated: November 7, 1996.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 96–29290 Filed 11–14–96; 8:45 am]

BILLING CODE 4160–18–P

Food and Drug Administration

[Docket No. 96P–0212]

Determination That Ibuprofen 200-Milligram Capsule Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that ibuprofen (Midol®) 200-milligram (mg) capsule was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDA's) for ibuprofen 200-mg capsule.

FOR FURTHER INFORMATION CONTACT: Andrea C. Masciale, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress passed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as ''the listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDA's do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

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