DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0228]

Draft Guidance for Industry and Food and Drug Administration Staff; the Review and Inspection of Premarket Approval Applications Under the Bioresearch Monitoring Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program.'' One of the performance goals, referenced in a letter to Congress from the Secretary of Health and Human Services that accompanied the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) legislation, includes a commitment to improve FDA's scheduling and timeliness of preapproval inspections. This draft guidance document is intended to assist applicants in understanding the process involved in the bioresearch monitoring (BIMO) review of the clinical and nonclinical information in their premarket approval application (PMA) and the process involved in any related inspections. Premarket notification (510(k)) submissions are not addressed in this draft guidance because a premarket inspection is not ordinarily conducted for 510(k)s. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by September 18, 2006.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Matthew J. Tarosky, Center for Devices and Radiological Health (HFZ–310), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–270–0243.

SUPPLEMENTARY INFORMATION:

I. Background

On October 26, 2002, MDUFMA (Public Law 107–250) was signed into law. Among other things, MDUMFA authorized the collection of user fees to improve the performance and predictability of FDA's device review program, including PMAs. FDA, in consultation with the regulated industry, agreed to dedicate user fees to helping the agency meet the performance goals outlined in a letter from the Secretary of Health and Human Services to Congress that accompanied the user fee legislation. One such goal included a commitment to ''improve the scheduling and timeliness of preapproval inspections.'' A portion of the user fees collected under MDUFMA will be used to help to cover the costs associated with the BIMO program review of the PMA and the performance of any clinical or nonclinical inspections. FDA will monitor its BIMO preapproval inspection program and include this information in its annual performance report to Congress.

This draft guidance provides information about the administrative process and timeframes within which the BIMO review of the PMA clinical and nonclinical sections should be completed. Use of this draft guidance should facilitate FDA's timely review and inspection of the PMA clinical and nonclinical information and improve the coordination of a preapproval inspection between the applicant and FDA.

II. Significance of Guidance

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 ''The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program.'' 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. To receive ''The Review and Inspection of Premarket Approval Applications under the Bioresearch Monitoring Program,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1602 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-related information. The CDRH web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520) (the PRA). The collections of information addressed in 21 CFR part 814 have been approved by OMB under OMB Control No. 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 8, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–9653 Filed 6–19–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; Comment Request; Environmental Factors in the Development of Polycystic Ovary Syndrome

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 January 20, 2006, pages 3310–3311 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 control number.

Proposed Collection: Title: Environmental Factors in the Development of Polycystic Ovary Syndrome.

Type of Information Collection Request: Revision of OMB No. 0925–0483 and expiration date 3/31/2006.

Need and Use of Information Collection: The purpose of this study is to identify a cohort of living female twin pairs in which at least one member is likely to have Polycystic Ovary Syndrome (PCOS) for future study. Potential participants (-2,200) will come from the Mid-Atlantic Twin Registry (MATR) and were chosen based on their answers to several questions (in a preliminary MATR survey) concerning irregular periods and a history of polycystic cystic ovaries. The instrument to be used here will be administered by telephone by professional interviewers at the MATR. It contains 17 simple and direct questions and will take about 10 minutes to complete. It contents deal with the frequency of menstrual periods, a history of polycystic ovaries, obesity, excess facial hair and other evidence of hyperandrogenism. Since this is such a short telephone survey, participants will receive no prior notification. Informed consent will be asked for verbally over the phone at the time of the interview. A; participants will be asked about their willingness to participate in future studies if their answers meet certain criteria. The major objectives of future studies using this cohort are to determine more reliable concordance rates for PCOS in monozygotic and diygotic twins, establish baseline heritability estimates, and develop hypotheses concerning possible pathogenetic and/or environmental factors. The findings from this study will aid in developing: (1) Genetic tests to identify high risk women; (2) preventative strategies; and (3) more effective therapies for PCOS and related syndromes such as type 2 diabetes, obesity, idiopathic hyperandrogenism, and male pattern baldness. *Frequency of Response:* One time. *Affected Public:* Individuals or households. *Type of Respondents:* Adult women. The annual reporting burden is as follows: *Estimated Number of Respondents:* 2,200; *Estimated Number of Responses Per Respondent:* 1; *Average Burden Hours Per Response:* 0.167; and *Estimated Total Annual Burden Hours Requested:* 122 per year for 3 more years. The annualized costs to respondents is estimated at $2,050.38. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the fuction of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality utility and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technology collection techniques or other forms of information technology.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Patricia C. Chulada, Clinical Research Scientist, Clinical Research Office, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–7736 or e-mail your request, including your address to: *chulada@niehs.nih.gov*.

Comments Due Date: Comments regarding this infomation collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: March 27, 2006.

Richard A. Freed,

NIEHS Associate Director for Management.

[FR Doc. 06–5527 Filed 6–19–06; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Aggression Prevention Among High-Risk Early Adolescents

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Aggression Prevention Among High-Risk Early Adolescents Study. *Type of Information Collection Request:* EXTENSION, OMB control number 0925–0523, expiration date 9/30/2006. *Use of Information:* This study will assess the efficacy of an in-school, group-mentoring intervention designed to foster academic engagement and prevent aggressive and deviant behavior among early adolescents (approximately ages 11–12). The primary objectives of the study are to determine if participation in a weekly group-mentoring program during 6th grade