Dated: October 1, 1997.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 97–27648 Filed 10–17–97; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 94N–0227]

Nandlal G. Rana; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) permanently debarring Mr. Nandlal G. Rana, 184 Parsonage Rd., Edison, NJ 08817, from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Rana was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Rana failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

EFFECTIVE DATE: October 20, 1997.

ADDRESSES: Application for termination of debarment to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Christine F. Rogers, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

On October 5, 1993, the United States District Court for the District of Maryland entered judgment against Mr. Nandlal G. Rana for one count of obstructing an agency proceeding, a Federal felony under 18 U.S.C. 1505.

As a result of this conviction, FDA served Mr. Rana by certified mail on February 17, 1995, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application, and offered him an opportunity for a hearing on the proposal. The proposal was based on a finding, under section 306(a)(2)(B) of the act (21 U.S.C. 335a(a)(2)(B)), that Mr. Rana was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Rana was provided 30 days to file objections and request a hearing. Mr. Rana did not request a hearing. His failure to request a hearing constitutes a waiver of his opportunity for a hearing and a waiver of any contentions concerning his debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(a)(2)(B) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Nandlal G. Rana has been convicted of a felony under Federal law for conduct relating to the regulation of a drug product.

As a result of the foregoing finding, Mr. Nandlal G. Rana is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 507, 512, or 802 of the act (21 U.S.C. 355, 357, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective October 20, 1997 (sections 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Rana, in any capacity, during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Rana, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Rana during his period of debarment.

Any application by Mr. Rana for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N–0227 and sent to the Dockets Management Branch (address above). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 1, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 97–27693 Filed 10–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee Meeting; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Cardiovascular and Renal Drugs Advisory Committee. This meeting was announced in the **Federal Register** of September 18, 1997. The amendment is being made to: Remove the second agenda item scheduled on October 23, 1997; add a closed session to the agenda scheduled on October 23, 1997; and provide a new location site for this closed session. There are no other changes. This amendment will be announced at the beginning of the open portion of the meeting.

FOR FURTHER INFORMATION CONTACT: Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), 419–259–6211, or Danyiel D'Antonio (HFD–21), 301–443–5455, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12533. Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 18, 1997 (62 FR 49015), FDA announced that a meeting of the Cardiovascular and Renal Drugs Advisory Committee would be held on October 23 and 24, 1997. This amendment is to provide an update to the information provided earlier pertaining to the October 23, 1997, meeting day. There are no changes for the October 24, 1997, meeting day. On page 49015, beginning in column 3, portions of the notice pertaining to the October 23, 1997, meeting day are amended to read as follows:

Location: October 23, 1997, 8:30 a.m. to 2 p.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD.

October 23, 1997, 2 p.m. to 5:30 p.m., Hyatt Regency Bethesda, Susquehanna/Severn Room, One Bethesda Metro Center, Bethesda, MD.

Agenda: On October 23, 1997, the committee will discuss basic statistical considerations for the evaluation of active control clinical trials.

Procedure: On October 23, 1997, from 8:30 a.m. to 2 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 16, 1997. Oral presentations from the public will be scheduled between approximately 8:30 a.m. and 9:30 a.m. on October 23, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 16, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On October 23, 1997, from 2 p.m. to 5:30 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The committee will discuss pending investigational new drug applications.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 10, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–27695 Filed 10–15–97; 11:17 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; 1997/98 World Health Organization Study of Health Behavior in School Children

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the National Institute of Child Health and Human Development (NICHD), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on Thursday, March 27, 1997, 14687–14688 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 (5 CFR 1320.5).

Proposed collection Title

Title: 1997/98 World Health Organization Health Behavior in School Children. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of this study is to analyze differences in risk factors and determinants of injuries and other health related behavior for the early- to mid-adolescent age group across the majority of developed countries. A representative U.S. school-based sample of adolescents is needed to participate in the international study. Data will be used to improve the quality of health promotion programs for youth. *Frequency of Response:* This is a one time study. *Affected Public:* Individuals or households. *Type of Respondents:* U.S. youth in grades 6 through 10. The annual reporting burden is as follows: *Estimated Number of Respondents:* 19,315; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours Per Response:* 0.71; and *Estimated Total Annual Burden Hours Requested:* 13,759. There are no Capital Costs, Operating Costs, and/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 function 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 technological collection techniques or other forms of information technology.

Written comments and/or suggestions regarding the items 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, D.C. 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: Mary D. Overpeck, DrPH, Epidemiology Branch, Division of Epidemiology, Statistics and Prevention Research, Building 6100, Room 7B03, 9000 Rockville Pike MSC 7510, Bethesda, MD 20892–7510, or call non-toll-free number (301) 496–1711.

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: September 19, 1997.

Benjamin E. Fulton,

Executive Officer, NICHD.

[FR Doc. 97–27671 Filed 10–17–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health; Notice of Meeting of the NIH Director's Advisory Panel on Clinical Research

Notice is hereby given that the NIH Director's Advisory Panel on Clinical Research, a group reporting to the Advisory Committee to the Director (ACD), National Institutes of Health (NIH), will meet in public session at the William H. Natcher Building (Building 45) Conference Center, Conference Room D, National Institutes of Health, Bethesda, Maryland 20892, on November 7, 1997 from 9:00 a.m. until approximately 3:00 p.m.

The goal of the Panel is to review the status of clinical research in the United States, and to make recommendations to the ACD about how to ensure its effective continuance. At this meeting items of special concern to the Panel will be discussed preparatory to submission of the Panel's final recommendations by the Panel Chair to the ACD in December, 1997.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other special accommodations, should contact the person named below in advance of the meeting.