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]

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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.