

of the Agency for Health Care Policy and Research (AHCPR) Contracts Review Committee, recommendations to the Administrator, AHCPR, regarding the technical merit of contract proposals submitted in response to a specific Request for Proposals regarding the Small Business Innovation Research (SBIR) Program.

The purpose of this contract is to continue the research that was initiated in Phase I of these SBIR contracts.

Agenda: The Committee meeting will be devoted entirely to the technical review and evaluation of contract proposals submitted in response to the above referenced Request for Proposals. The Administrator, AHCPR, has made a formal determination that this meeting will not be open to the public. This action is necessary to protect the free and full exchange of views in the contract evaluation process and safeguard confidential proprietary information, and personal information concerning individuals associated with the proposals that may be revealed during the meeting. This action is taken in accordance with section 10(d) of the Federal Advisory Committee Act, 5 U.S.C., Appendix 2, 5 U.S.C. 522(b)(c)(6), 41 CFR 101-6.1023 and Department procurement regulations, 48 CFR 315.604(d).

Anyone wishing to obtain information regarding this meeting should contact Charles Darby, Center for Quality Measurement and Improvement, Agency for Health Care Policy and Research, 2101 East Jefferson Street, Suite 502, Rockville, Maryland 20852, 301/594-1349, X1316.

Dated: August 20, 1997.

John M. Eisenberg,

Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N-0071]

Amirul Islam; Final 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. Amirul Islam, 120 Adams St., Deer Park, NY 11729, 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. Islam was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Islam has waived his

opportunity for a hearing concerning this action.

EFFECTIVE DATE: August 27, 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: Leanne Cusumano, 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

Mr. Amirul Islam, a former vice president of technical services for Halsey Drug Co., Inc., (Halsey) and supervisor of Halsey's Quality Control Laboratory, pled guilty to, and on October 19, 1994, was sentenced for, obstructing an agency proceeding, a Federal felony under 18 U.S.C. 1505. The basis for this conviction was as follows: On or about August 29, 1989, Mr. Islam gave FDA inspectors a raw material inventory card for fenoprofen calcium which he knew to be false. The inventory card stated that Halsey had received 50 kilograms of fenoprofen calcium on September 11, 1987. In fact, Halsey had received only half that amount. Mr. Islam knew that the purpose of the falsified inventory card was to conceal from FDA the fact that Halsey did not have enough raw material from the September 11, 1987, shipment to manufacture pilot batches in the sizes represented in abbreviated new drug applications (ANDA's) for fenoprofen calcium 200 milligram (mg) capsules, fenoprofen calcium 300 mg capsules, and fenoprofen calcium 600 mg tablets.

Mr. Islam is subject to debarment based on a finding, under section 306(a) of the act (21 U.S.C. 355a(a)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Islam's conduct related to the regulation of a drug product because, in presenting false raw material inventory records, he obstructed FDA's regulation of generic drugs by representing that the ANDA's submitted by Halsey were true in all material respects.

FDA initiated debarment proceedings against Mr. Islam on or about May 15, 1995. A person subject to debarment is entitled to an opportunity for an agency hearing on disputed issues of material fact under section 306(i) of the act, but Mr. Islam waived his opportunity for a

hearing and any contentions concerning his debarment by letter received by FDA on April 22, 1997.

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. Amirul Islam 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 findings and based on his notification of acquiescence, Mr. Amirul Islam is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 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 August 27, 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. Islam, 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. Islam, 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 ANDA's or abbreviated antibiotic drug applications submitted by or with the assistance of Mr. Islam during his period of debarment.

Any application by Mr. Islam for termination of debarment under section 306(d) of the act should be identified with Docket No. 95N-0071 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: August 19, 1997.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

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