

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

President's Committee for People With Intellectual Disabilities (PCPID): Notice of Meeting

AGENCY: President's Committee for People With Intellectual Disabilities (PCPID), HHS.

ACTION: Notice of meeting.

DATES: Thursday, October 16, from 8:30 a.m. to 1:30 p.m. The full Committee meeting of the President's Committee for People With Intellectual Disabilities will be open to the public on Thursday, October 16, from 8:30 a.m. to 1:30 p.m.

ADDRESSES: The meeting will be held at the Aerospace Center Building, Aerospace Auditorium, 6th Floor East, 370 L'Enfant Promenade, SW., Washington, DC 20447. Individuals with disabilities who need special accommodations in order to attend and participate in the meeting (*i.e.*, interpreting services, assistive listening devices, materials in alternative format) should notify Executive Director, Sally Atwater, at 202-619-0634 no later than October 1, 2003. Effort will be made to meet special requests received after that date, but availability of special needs accommodations to respond to these requests cannot be guaranteed. All meeting sites are barrier free.

Agenda: The Committee plans to discuss critical issues relating to individuals with intellectual disabilities concerning education and transition, family services and support, public awareness, employment, and assistive technology and information.

FOR FURTHER INFORMATION CONTACT: Sally Atwater, Executive Director, President's Committee for People with Intellectual Disabilities, Aerospace Center Building, Suite 701, 370 L'Enfant Promenade, SW., Washington, DC 20447, Telephone—(202) 619-0634, Fax—(202) 205-9519, E-mail—satwater@acf.hhs.gov.

SUPPLEMENTARY INFORMATION: The PCPID acts in an advisory capacity to the President and the Secretary of the U.S. Department of Health and Human Services on a broad range of topics relating to programs, services, and supports for persons with intellectual disabilities. The Committee, by Executive Order, is responsible for evaluating the adequacy of current practices in programs, services and supports for persons with intellectual disabilities, and for reviewing legislative

proposals that impact the quality of life that is experienced by citizens with intellectual disabilities and their families.

Dated: September 25, 2003.

Sally Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1995N-0071]

Amirul Islam; Grant of Special Termination; Final Order Terminating Debarment

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) granting special termination of the debarment of Amirul Islam. FDA bases this order on a finding that Mr. Islam provided substantial assistance in the investigations or prosecutions of offenses relating to a matter under FDA's jurisdiction and that special termination of Mr. Islam's debarment serves the interest of justice and does not threaten the integrity of the drug approval process.

DATES: This order is effective October 9, 2003.

ADDRESSES: Comments should reference Docket No. 1995N-0071 and be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nicole K. Mueller, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In a **Federal Register** notice dated August 27, 1997 (62 FR 45423), Amirul Islam, the former vice president of technical services for Halsey Drug Co. Inc. (Halsey), and supervisor of Halsey's Quality Control Laboratory, was permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 306(c)(1)(B) and (c)(2)(A)(ii) of the act (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and section 201(dd) of the act (21 U.S.C.

321(dd)). The debarment was based on FDA's finding that Mr. Islam was convicted of a felony under Federal law for conduct relating to the development or approval of any drug product, or otherwise relating to the regulation of a drug product (21 U.S.C. 335a(a)(2)). On December 12, 1997, Mr. Islam applied for special termination of debarment under section 306(d)(4)(a) of the act, as amended by the Generic Drug Enforcement Act (GDEA).

Under section 306(d)(4)(C) and (D) of the act, FDA may limit the period of debarment of a permanently debarred individual if the agency finds that: (1) The debarred individual has provided substantial assistance in the investigation or prosecution of offenses described in section 306(a) or (b) of the act or relating to a matter under FDA's jurisdiction, (2) termination of the debarment serves the interest of justice, and (3) termination of the debarment does not threaten the integrity of the drug approval process. Special termination of debarment is discretionary with FDA.

FDA considers a determination by the Department of Justice concerning the substantial assistance of a debarred individual conclusive in most cases. Mr. Islam cooperated with the Department of Justice investigations and prosecutions of others, as substantiated by the letters submitted to the agency by the Assistant U.S. Attorney who prosecuted Mr. Islam's case. Accordingly, FDA finds that Mr. Islam provided substantial assistance as required by section 306(d)(4)(C) of the act.

The additional requisite showings that termination of debarment serves the interest of justice and poses no threat to the integrity of the drug approval process are difficult standards to satisfy. In determining whether these have been met, the agency weighs the significance of all favorable and unfavorable factors in light of the remedial, public health-related purposes underlying debarment. Termination of debarment will not be granted unless, weighing all favorable and unfavorable information, there is a high level of assurance that the conduct that formed the basis for the debarment has not recurred and will not recur, and that the individual will not otherwise pose a threat to the integrity of the drug approval process.

The evidence presented to FDA in support of termination shows that Mr. Islam was convicted for a first offense, that he has no prior or subsequent convictions for conduct described under the GDEA and has committed no other wrongful acts affecting the drug approval process, and that his character