

this order on a finding that Mr. Elsharaiha was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Elsharaiha failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

**EFFECTIVE DATE:** September 29, 2000.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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, 301-594-5640.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On March 4, 1994, the U.S. District Court for the District of Maryland entered judgment against Mr. Elsharaiha for one count of making false declarations before a grand jury, a Federal felony offense under 18 U.S.C. 1623.

As a result of this conviction, FDA published in the **Federal Register** of January 19, 1999 (64 FR 2905), a notice proposing to permanently debar Mr. Elsharaiha from providing services in any capacity to a person that has an approved or pending drug product application, and offering 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. 355a(a)(2)(B)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Elsharaiha was provided 30 days to file objections and request a hearing. Mr. Elsharaiha 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 of the 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. Rami Elsharaiha 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. Rami Elsharaiha is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application

under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective September 29, 2000, (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Mr. Elsharaiha, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Elsharaiha, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Elsharaiha during his period of debarment.

Any application by Mr. Elsharaiha for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N-0371 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: September 11, 2000.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-2674]

**Jay Marcus; 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) debarring Mr. Jay Marcus for 5 years 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. Marcus was convicted of a felony under Federal law for conspiracy to defraud the United States. Mr. Marcus failed to request a hearing and, therefore, has waived his

opportunity for a hearing concerning this action.

**EFFECTIVE DATE:** September 29, 2000.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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 21, 1994, the U.S. District Court for the District of Maryland accepted Mr. Marcus' plea of guilty to one count of conspiracy to defraud the United States under 18 U.S.C. 371 and sentenced Mr. Marcus for the crime.

As a result of this conviction, FDA published in the **Federal Register** of October 15, 1999 (64 FR 55944), a proposal to debar Mr. Marcus for a period of 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Mr. Marcus an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(b)(2)(B)(i) of the act (21 U.S.C. 355a(b)(2)(B)(i)), that Mr. Marcus was convicted of a felony under Federal law for conspiracy to defraud the United States. Mr. Marcus was provided 30 days to file objections and request a hearing. Mr. Marcus 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(b)(2)(B)(i) of the act, and under authority delegated to her (21 CFR 5.99), finds that Mr. Jay Marcus has been convicted of a felony under Federal law for conspiracy to defraud the United States.

As a result of the foregoing finding, Mr. Jay Marcus is debarred for a period of 5 years 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 September 29, 2000 (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or

pending drug product application who knowingly uses the services of Mr. Marcus in any capacity during his period of debarment, will be subject to civil money penalties. If Mr. Marcus, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Marcus during his period of debarment.

Any application by Mr. Marcus for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 99N-2674 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: September 11, 2000.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 94N-0424]

#### Mohammad Uddin; 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 debaring Mr. Mohammad Uddin 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. Uddin was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Uddin failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

**EFFECTIVE DATE:** September 29, 2000.

**ADDRESSES:** Submit applications for termination of debarment to the Dockets Management Branch (HFA-305), Food

and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**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 November 19, 1993, the United States District Court for the District of Maryland entered judgment against Mr. Uddin for one count of obstruction of an agency proceeding, a Federal felony offense under 18 U.S.C. 1505.

As a result of this conviction, FDA published in the **Federal Register** of January 12, 1999 (64 FR 1809), a notice proposing to permanently debar Mr. Uddin from providing services in any capacity to a person that has an approved or pending drug product application and offering 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. 355a(a)(2)(B)), that he was convicted of a felony under Federal law for conduct relating to the regulation of a drug product. Mr. Uddin was provided 30 days to file objections and request a hearing. Mr. Uddin 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. Mohammad Uddin 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. Mohammad Uddin is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective September 29, 2000 (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. Uddin, in any capacity, during his period of debarment, will be subject to civil money penalties. If Mr. Uddin, 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. In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Uddin during his period of debarment.

Any application by Mr. Uddin for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 94N-0424 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: September 11, 2000.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 00-25088 Filed 9-28-00; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98F-0290]

#### The Dow Chemical Co.; Withdrawal of Food Additive Petition

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to a future filing, of a food additive petition (FAP 8B4586) proposing that the food additive regulations be amended to provide for the safe use of certain olefin basic copolymers, derived from ethylene and alpha monomers with eight or fewer carbon atoms, as articles or as components of articles intended for use in contact with food.

**FOR FURTHER INFORMATION CONTACT:** Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3086.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of May 7, 1998 (63 FR 25212), FDA announced that a food additive petition (FAP 8B4586) had been filed by the Dow Chemical Co., 2030 Dow Center, Midland, MI 48674. The petition proposed to amend the food additive