

and was a material participant in offenses for which another person is being debarred. Dr. Borison has failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective September 30, 2003.

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

FOR FURTHER INFORMATION CONTACT: Mary Catchings, 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 8, 1998, the Superior Court for the County of Richmond, State of Georgia, accepted Dr. Borison's plea of guilty and entered judgment against him for 36 counts of criminal offenses under Georgia State law for racketeering, theft, and false statements and representations.

As a result of this conviction, FDA served Dr. Borison by certified mail on December 5, 2002, a notice proposing to debar him for 10 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Dr. Borison an opportunity for a hearing on the proposal. The debarment proposal was based on findings: (1) Under section 306(b)(2)(B)(ii) of the act (21 U.S.C. 335a(b)(2)(B)(ii)) that Dr. Borison was convicted of felonies under State law for racketeering, theft, and false statements and representations; and (2) under section 306(b)(2)(B)(iii) of the act that Dr. Borison was a material participant in offenses leading to the conviction and debarment of another individual. Dr. Borison was provided 30 days to file objections and to request a hearing. Dr. Borison 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) of the act, and under authority delegated to her (21 CFR 5.34), finds that Dr. Richard L. Borison: (1) Has been convicted of a felony under State law for racketeering, theft, and false statements and representations; and (2) was a material

participant in offenses leading to the conviction of another individual.

As a result of the foregoing findings, Dr. Richard L. Borison is debarred for 10 years (two periods of 5 years, to run consecutively, based on his conviction for State felonies and his role as a material participant in the offenses leading to the conviction and debarment of another individual) from providing services in any capacity to a person that has 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)(see sections 306(c)(1)(B) and (c)(2)(A)(iii) 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 Dr. Borison in any capacity during his period of debarment will be subject to civil money penalties. If Dr. Borison, 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 Dr. Borison during his period of debarment.

Any application by Dr. Borison for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 2000N-1530 and sent to the Division of Dockets Management (see **ADDRESSES**). 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 4, 2003.

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. 2000N-1428]

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

DATES: This order is effective September 30, 2003.

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

FOR FURTHER INFORMATION CONTACT: Mary Catchings, 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 28, 1998, the U.S. District Court for the District of Maryland accepted Mr. Suhas V. Sardesai's plea of guilty to one count of distributing an adulterated drug into interstate commerce, a Federal felony offense under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)).

As a result of this conviction, FDA served Mr. Sardesai by certified mail on July 24, 2002, 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. The proposal also offered Mr. Sardesai 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. Sardesai was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the act. Mr. Sardesai was provided 30 days to file objections and request a hearing. Mr. Sardesai 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 5.34), finds that Mr. Suhas V.