DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0377] (formerly Docket No. 2007N–0299)

Allyn M. Norman; 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 Dr. Allyn M. Norman 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 Dr. Norman was convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product or otherwise relating to the regulation of drug products under the act, and that the type of conduct that served as the basis for the conviction undermines the process for the regulation of drugs. Dr. Norman failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective June 12, 2009.

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: Robert L. Hummel, Sr., Division of Compliance Policy (HFC–230), Office of Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6845.

SUPPLEMENTARY INFORMATION:

I. Background

On October 28, 2002, the U.S. District Court for the Western District of New York accepted Dr. Norman's plea of guilty to one count of failure to maintain adequate and accurate records relating to the use of investigational new drugs, a Federal misdemeanor offense under 21 U.S.C. 331(e) and 333(a)(1). On February 5, 2003, the U.S. District Court for the Western District of New York entered a judgment of conviction against Dr. Norman for this offense.

The basis of this conviction was Dr. Norman's creation and submission of falsified study data in required reports to the sponsor of an investigational new drug application (IND) study, in violation of section 505(i) of the act (21 U.S.C. 355(i)) and 21 CFR 312.62(a) and (b). Dr. Norman failed to conduct the study according to the approved protocol, reported the enrollment of nonexistent subjects in the study, and fabricated all of the pertinent study records associated with these subjects. Dr. Norman's failure to comply with the requirements of the act and FDA regulations concerning the conduct of an IND study is the type of conduct that undermines confidence in the results of clinical studies that are relied on in the approval process for drug products.

As a result of Dr. Norman's conviction, FDA sent to Dr. Norman, by certified letter on October 10, 2007, a proposal to debar Dr. Norman for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The letter also offered Dr. Norman notice of an opportunity for a hearing on the proposal in accordance with section 306 of the act (21 U.S.C. 335a) and 21 CFR part 12. FDA based the debarment proposal on the findings, under section 306(b)(2)(B)(i)(I) of the act, that Dr. Norman was convicted of a misdemeanor under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product or otherwise relating to the regulation of drug products under the act, and that the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs. The letter notified Dr. Norman that he had 30 days from the date of receipt of the letter to request a hearing. Dr. Norman 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 Acting Director, Office of Enforcement, Office of Regulatory Affairs, under section 306(b)(2)(B)(i)(I) of the act and under authority delegated to the Acting Director (Staff Manual Guide 1410.35), finds that Dr. Allyn M. Norman has been convicted of a misdemeanor under Federal law for failure to maintain adequate and accurate records relating to the use of investigational new drugs, that Dr. Norman's conduct relates to the development or approval, including the process for development or approval, of a drug product or otherwise relates to the regulation of drug products under the act, and that Dr. Norman's conduct, which served as the basis for his conviction, is the type of conduct that undermines the process for the regulation of drugs.

As a result of the foregoing findings, Dr. Norman is debarred for 5 years 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 (see **DATES**) (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. Norman, 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. 355b(a)(6))). If Dr. Norman, 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 Dr. Norman during his period of debarment.

Any application by Dr. Norman for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2007–N–0377 (formerly Docket No. 2007N–0299) 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: June 4, 2009.

Alyson L. Saben,

Acting Director, Office of Enforcement, Office of Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.