DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Biologics Evaluation and Researc
1401 Rockville Pike
Rockville MD 20852-1448

August 1, 2005

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas M. Rodgers, Jr.
4010 Beechwood Drive
Atlanta, GA 30327

Dear Mr. Rodgers:

This letter confirms receipt of the letter dated January 16, 2003, submitted on your behalf by Colin J. Zick of the Foley Hoag law firm, that requested a hearing on the Food and Drug Administration's (FDA's) December 17, 2002, proposal to issue an order debarring you for a five year period from providing services in any capacity to a person that has an approved or pending drug product application, including but not limited to a biologics license application.

In accordance with Title 21, Code of Federal Regulations, Part 12.24(b)(1), a hearing will only be granted if materials are submitted showing that there is a genuine and substantial issue of fact for resolution at a hearing. Your hearing request has been reviewed, and the FDA has determined that the request did not raise any genuine and substantial issues of fact to grant a hearing on the debarment. Therefore, your request for hearing has been denied, and FDA has proceeded to issue a final order under section 306(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 335a(b), debarring you for a period of five years from providing services in any capacity to a person that has an approved or pending drug product application, including but not limited to a biologics license application. A copy of the final debarment order is enclosed.

Sincerely,

Mary A. Malarkey
Director
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research

Enclosure

cc: Colin J. Zick
Foley Hoag LLP
155 Seaport Boulevard
Boston, MA 02210

as severe allergic reactions. However, the risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 5–17 years of age have reported mild reactions, including:

- Runny nose, nasal congestion or cough;
- Headache and muscle aches;
- Fever;
- Abdominal pain or occasional vomiting or diarrhea.

Some adults 18–49 years of age have reported:

- Runny nose or nasal congestion;
- Sore throat;
- Cough, chills, tiredness/weakness;
- Headache.

These symptoms did not last long and went away on their own. Although they can occur after vaccination, they may not have been caused by the vaccine.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is within a few minutes to a few hours after vaccination.
- If rare reactions occur with any new product, they may not be identified until thousands, or millions, of people have used it. Over two million doses of LAIV have been distributed since it was licensed, and no serious problems have been identified. Like all vaccines, LAIV will continue to be monitored for unusual or severe problems.

7. What if there is a severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS Web site at *http://www.vaers.hhs.gov*, or by calling 1–800–822–7967.

VAERS does not provide medical advice.

8. The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1–800–338–2382 or visit their Web site at *http://www.hrsa.gov/osp/vicp.*

9. How can I learn more?

- Ask your immunization provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):

—Call 1–800–232–4636 (1–800–CDC–INFO)

—Visit CDC's Web site at *http://www.cdc.gov/flu.*

Department of Health and Human Services, Centers for Disease Control and Prevention, National Immunization Program.

Vaccine Information Statement, Live, Intranasal Influenza Vaccine, (6/18/05) (Interim), 42 U.S.C. 300aa–26.

Dated: July 22, 2005.

James D. Seligman,

Associate Director for Program Services, Centers for Disease Control and Prevention.

[FR Doc. 05–14924 Filed 7–27–05; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002N–0510]

Thomas M. Rodgers, Jr.; Denial of Hearing; Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Mr. Thomas M. Rodgers, Jr.'s request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the act) debarring Mr. Thomas M. Rodgers, Jr., for 5 years from providing services in any capacity to a person that has an approved or pending drug product application including, but not limited to, a biologics license application. FDA bases this order on a finding that Mr. Rodgers was convicted of three misdemeanors under Federal law for conduct relating to the regulation of a drug product under the act, and that the type of conduct that served as the basis for the convictions undermines the process for the regulation of drugs. Mr. Rodgers failed to file with FDA information and analyses sufficient to create a basis for a hearing concerning this action. Therefore, FDA finds that there is no genuine and substantial issue of fact to grant a hearing on the debarment.

DATES: This order is effective July 28, 2005.

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: Kathleen Swisher, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

On May 4, 2000, the U.S. District Court for the District of Massachusetts accepted a plea of guilty from Mr. Thomas M. Rodgers, Jr. for three counts charged as Federal misdemeanors under section 303(a)(1) of the act (21 U.S.C. 333(a)(1)): (1) Owning and operating an unregistered facility for the manufacture of drugs (301(p) of the act (21 U.S.C. 331(p))); (2) shipping an unapproved new drug in interstate commerce (301(d) of the act; and (3) shipping an adulterated drug in interstate commerce (301(a) of the act).Mr. Rodgers was the Chairman of the Board of Directors and majority shareholder of Private Biologicals Corporation (PBC). PBC, which was not registered as an establishment engaged in the manufacture of drugs, was in the business of producing a product identified as "LK–200," an unapproved new drug which PBC and its agents intended to be used in the treatment of a variety of diseases, including various forms of cancer. Mr. Rodgers caused LK–200, an unapproved and adulterated new drug, to be introduced into interstate commerce.

As a result of Mr. Rodgers' conviction, FDA sent to Mr. Rodgers by certified letter on December 17, 2002, a proposal to debar Mr. Rodgers for 5 years from providing services in any capacity to a person that has an approved or pending drug product application, including but not limited to, a biologics license application. The letter also provided Mr. Rodgers notice of an opportunity for a hearing on the proposal in accordance

with section 306 of the act (21 U.S.C. 335a) and part 12 (21 CFR part 12). FDA based the proposal on the findings under section 306(b)(2)(B)(i) of the act (21 U.S.C. 335a(b)(2)(B)(i)) that Mr. Rodgers was convicted of three misdemeanors under Federal law for conduct relating to the regulation of a drug product under the act and that the type of conduct that served as the basis for the convictions undermines the process for the regulation of drugs.

The certified letter also informed Mr. Rodgers that his request for a hearing could not rest upon mere allegations, denials, or general descriptions of positions and contentions, but must present specific facts showing that there was a genuine and substantial issue of fact requiring a hearing. The letter also informed Mr. Rodgers that the facts underlying his conviction were not at issue and that the only material issue is whether he was convicted of misdemeanors under Federal law as alleged in the letter, and, if so, whether, as a matter of law, the convictions permit his debarment.

In a letter dated January 16, 2003, Mr. Rodgers, through his legal counsel, requested a hearing on the proposed debarment. The request for a hearing included the following objections to the debarment: (1) Mr. Rodgers' actions did not continue to undermine the process for the regulation of drugs by FDA; and (2) the descriptions of Mr. Rodgers' conduct in the proposal to debar letter were not found in the Information filed in the U.S. District Court of Massachusetts (the Information), despite the letter's statement to the contrary.

II. Denial of Hearing

In his request for a hearing, Mr. Rodgers argued that the previous conduct that led to his conviction does not continue to undermine FDA regulatory processes, and that such a determination is necessary to debar him under the debarment statute. Mr. Rodgers asserts that the proposal to debar did not reference present or future regulatory processes that are or will be undermined; rather, the proposal to debar included a statement that only referenced past processes. According to Mr. Rodgers, without a finding that the conduct that resulted in his conviction has a continuing impact on the regulation of drugs, the elements of the debarment statute have not been met. FDA disagrees with Mr. Rodgers' assertion.

Mr. Rodgers does not deny that type of conduct for which he was convicted is the "type of conduct" that undermines the process for the regulation of drugs, part of the statutory standard for permissive debarment under section 306(b)(2)(B) of the act. Instead, he argues that the statutory language does not mean what it says but rather that it means the agency must establish that his conduct which served as a basis for his conviction continues to undermine the regulation of drugs. Mr. Rodgers' argument is totally without merit. The agency notes that Mr. Rodgers' argument is a legal one, and does not state grounds to grant Mr. Rodger's request for a hearing (See § 12.24(b)(1)). We address Mr. Rodgers' legal argument below.

Sections 306(b)(2)(B)(i) and (c)(2)(A)(iii) of the act permit FDA to debar an individual for up to 5 years if the FDA Commissioner (in exercising his authority delegated from the Secretary) finds first that the individual was convicted of, among other things, a misdemeanor under Federal law for conduct relating to the regulation of any drug product, and second that "the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs." Mr. Rodgers challenges the basis for the second finding, arguing that the debarment statute requires the agency to find that the conduct on which the convictions were based continue to undermine the regulatory process for drugs. Mr. Rodgers, in effect reads a continuing harm requirement into the statute.

Mr. Rodgers' argument relies solely on the present tense of the word "undermines." In focusing exclusively on verb tense, Mr. Rodgers ignores the subject of the statutory language and offers an interpretation contradicted by the plain language of the debarment statute.

Under well-established principles of statutory construction, the starting point in determining the meaning of a statute is the language of the statute itself (See, e.g., *Watt* v. *Alaska*, 451 United States 259, 265–66 (1981) (citations omitted)). The language of section 306(b)(2)(B)(i) of the act is clear. It states that "the type of conduct which served as the basis for the conviction undermines the process for the regulation of drugs." The subject of the verb "undermines" in the relevant statutory language is "the type of conduct," not the conduct of the individual facing debarment. Because the statute refers to a general category of conduct, the statute uses the present tense in the term "undermines" to permit debarment for conduct that is of a type that in general undermines the process for the regulation of drugs, regardless of whether the particular conduct that gave rise to the misdemeanor conviction continues to undermine the regulation of drugs. The statute does not require that the specific criminal acts that the individual committed continue to undermine the regulatory process.

Mr. Rodgers' contention that the use of the term "undermines" requires a continuing harm as a result of his conduct reads the express reference to a type of conduct out of the statute and reads into the statute the words "continues to undermine" that simply are not there. Even though the statute states that the type of conduct at issue is the type of conduct that "served as the basis for the conviction," this reference to the past conduct of the individual does not mean that the agency must establish that the past conduct continues to undermine the regulation of drugs to subject the individual to permissive debarment under section 306(b)(2)(B)(i).

It is clear that the type of conduct that served as the basis for Mr. Rodgers' conviction (failure to register a drug facility and shipping unapproved and adulterated drugs in interstate commerce) are types of conduct that undermine, in a general way, the process for regulating drugs. These statutory requirements are core requirements in the act's regulatory scheme for drugs.

Debarment is intended to protect the integrity of the drug process. In enacting the debarment statute, Congress recognized "a need to establish procedures to bar individuals who have been convicted of crimes pertaining to the regulation of drug products from working for companies that manufacture or distribute such products." Generic Drug Enforcement Act of 1992, Public Law 102–282, Section 1(c) (*emphasis added*), quoted in *Bae* v. *Shalala*, 44 F.3d 489, 493 (7th Cir. 1995). Congress concluded that in order to ensure the integrity of the drug approval process and to protect public health, it was necessary, among other things, to unequivocally exclude from the drug industry those individuals who had previously engaged in fraudulent or corrupt acts with respect to the regulation of drugs (65 FR 3458, January 21, 2000) (citing H.R. Rep. No. 102–272, 102d Cong., 1st Sess., at 14 (1991)). The application of permissive debarment to Mr. Rodgers is consistent with this purpose and is not contingent on a finding that his conduct continues to undermine the regulation of drugs.

Mr. Rodgers cites *Bae* v. *Shalala*, 44 F. 3d at 493 in support of his position, noting that the *Bae* court found that the Congressional purpose behind enactment of the debarment provisions was not punishment, but the prevention of present and future problems. In that

case, the Seventh Circuit held that the debarment statute is remedial rather than punitive in nature, but noted further that a law's general deterrent effect is consistent with a primarily remedial purpose (See id. at 494). The *Bae* court contrasted the general deterrent effect of the debarment statute with legislation intended to effect specific deterrence, noting that the latter "aims to change a particular individual's behavior through negative reinforcement." This description of laws aimed at specific deterrence also characterizes Mr. Rodgers' interpretation of the debarment statute: His interpretation ties debarment to the continuing harm from the behavior of the particular individual facing debarment, rather than to a type of behavior that in general undermines drug regulation. In contrast, an interpretation of the term "undermines" to allow debarment for conduct with a general tendency to undermine the regulation of drugs is consistent with the statute's remedial goal of protecting the processes for the regulation of drugs by deterring all individuals from engaging in damaging conduct presently or in the future. See id.; see also *DiCola* v. *FDA*, 77 F. 3d 504, 506–508 (D.C. Cir. 1996) (discussing remedial purpose behind debarment statute).

Mr. Rodgers also argues that contrary to assertions included in the proposal to debar, the following statements are not included in the Information: (1) A detailed description of the LK–200 product (e.g., that it was a supernatant of white blood cell materials or that it meets the definition of a drug product); or (2) any claim that FDA was prevented from obtaining accurate and complete information necessary to regulate the drug process by Mr. Rodgers.

Mr. Rodgers' objection (that Mr. Rodgers' conduct described in the December 17, 2002, proposal to debar is not explicitly stated in the Information) does not raise a genuine and substantial issue of fact as to whether Mr. Rodgers was convicted of misdemeanors under Federal law or whether, as a matter of law, the convictions permit Mr. Rodgers' debarment. Mr. Rodgers does not deny the accuracy of the statements made in the proposal to debar, only that the descriptions of his conduct are not found in the Information.

Mr. Rodgers was convicted of three counts of violating the act, specifically section 301(p), (d), and (a), for owning and operating an unregistered facility for the manufacture of drugs; shipping an unapproved new drug in interstate commerce; and shipping an adulterated drug in interstate commerce (see, e.g., April 4, 2000, plea agreement letter from the U.S. Department of Justice U.S. Attorney, District of Massachusetts re: *United States* v. *Thomas M. Rodgers, Jr.*, whereby Mr. Rodgers expressly and unequivocally admits that Mr. Rodgers in fact committed the crimes charged in the Information, and is in fact guilty of those offenses; see also 68 FR 46197, at 46198, August 5, 2003, Thomas Ronald Theodore, Debarment Order, description of the LK–200 drug product). It is clear that there is no genuine and substantial issue of fact regarding whether Mr. Rodgers was convicted.

In accordance with § 12.24(b)(1), a hearing will only be granted if materials are submitted showing that there is a genuine and substantial issue of fact for resolution at a hearing. For the reasons set forth previously, FDA finds that Mr. Rodgers failed to identify any genuine and substantial issue of fact justifying a hearing. In addition, Mr. Rodgers' legal arguments do not create a basis for a hearing, and, in any event, are without merit. Accordingly, the Commissioner denies Mr. Rodgers' request for a hearing.

III. Findings and Order

Therefore, the Commissioner, under section 306(b)(2)(B)(i) of the act, and under the authority delegated to the Commissioner of Food and Drugs, finds that Mr. Thomas M. Rodgers, Jr., has been convicted of three misdemeanors under Federal law for conduct relating to the regulation of a drug product under the act and that Mr. Rodgers' conduct which served as the basis for his conviction is the type of conduct that undermines the process for the regulation of drugs (21 U.S.C. 335a(b)(2)(B)(i)).

As a result of the foregoing findings, Mr. Thomas M. Rodgers, Jr. 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 sections 351 of the Public Health Service Act (42 U.S.C. 262). Any person with an approved or pending drug product application including, but not limited to, a biologics license application, who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Rodgers, in any capacity, during Mr. Rodgers' debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Mr. Rodgers, during his debarment, provides services in any capacity to a person with an approved or pending drug product application, including but not limited to, a biologics license application, Mr. Rodgers 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 Mr. Rodgers during Mr. Rodgers' debarment (section 306(c)(1)(B) of the act).

Any application by Mr. Rodgers for termination of debarment under section 306(d)(4) of the act should be identified with the Docket No. 2002N–0510 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies (21 CFR 10.20(a)). 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: July 20, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–14967 Filed 7–27–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0410] (formerly Docket No. 03E–0410)

Determination of Regulatory Review Period for Purposes of Patent Extension; ZUBRIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ZUBRIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term