



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

December 17, 2002

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

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

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

**PROPOSAL TO DEBAR**  
**NOTICE OF OPPORTUNITY FOR HEARING**  
**Docket No. 02N-0510**

Dear Mr. Rodgers:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order debaring you for 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. FDA bases this proposal on its finding that you were convicted of three misdemeanors under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act), and the conduct that served as the basis for the convictions undermines the process for the regulation of drugs. This letter also offers you an opportunity for a hearing on the proposal.

Conduct Related to Conviction

On May 4, 2000, the United States District Court for the District of Massachusetts accepted your plea of guilty and entered a judgment against you for three counts of violating sections 301(p), 301(d), and 301(a) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 331(p), 331(d), and 331(a), for operating an unregistered drug facility, interstate distribution of an unapproved new drug, and interstate distribution of an adulterated drug. These were charged as Federal misdemeanors under section 303(a)(1) of the Act, 21 U.S.C. 333(a)(1).

According to the Information filed in the United States District Court for the District of Massachusetts, you were the Chairman of the Board and majority shareholder of Private Biologicals Corporation (PBC). PBC was in the business of producing an unapproved drug product named LK-200. The product was a supernatant of white blood cell material, and was distributed for use in treating cancer as well as other diseases. LK-200 meets the definition of a drug product within the meaning of section 201(dd) of the Act, 21 U.S.C. 321(dd). PBC adulterated LK-200 in that the facilities and controls used in manufacture did not conform with

02N-0510

NPH 1

Page 2 - Mr. Thomas M. Rodgers, Jr.

current good manufacturing practice to assure that the product met the requirements of the Act as to safety and that LK-200 had the identity, strength, and quality it was represented to possess. In addition, you never registered the PBC manufacturing facility located in Woburn, Massachusetts. Moreover, you never sought approval to distribute the LK-200 product, and did not request an investigational exemption to distribute the product.

#### FDA's Finding

Sections 306(b)(2)(B)(i) and 306(c)(2)(A)(iii) of the Act, 21 U.S.C. §§ 335a(b)(2)(B)(i) and 335a(c)(2)(A)(iii), permits the debarment of up to five years for an individual found convicted of, among other things, a misdemeanor under Federal law for conduct relating to the regulation of any drug product, if the conduct that is the basis for the conviction undermines the process for the regulation of drugs. We find that you have been convicted of three misdemeanors under Federal law for conduct relating to the regulation of a drug product. Specifically, your convictions involved the operation of an unregistered facility and the distribution of a drug product that was both unapproved and adulterated.

In order for FDA to adequately and effectively regulate the development and approval of drug products, FDA requires that drug manufacturers register with FDA upon the initiation of drug product manufacturing, and that prior to interstate distribution of drug products, manufacturers submit and receive approval of a drug product application or receive an investigational exception to distribute the drug product prior to approval. Such facility registration and application review and approval is crucial for FDA to assure, among other things, the safety, purity, and potency of drug products and that drug products are manufactured in an appropriate facility. Due to your wrongful conduct, FDA was prevented from obtaining accurate and complete information necessary to regulate the drug process, and therefore, FDA's process for the regulation of drug products was undermined.

#### Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(b)(2)(B)(i) of the Act, 21 U.S.C. 335a(b)(2)(B)(i), debarring you 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 offenses for which you were convicted created a potential risk to the public health, and due to the nature and seriousness of the offenses, FDA proposes that your debarment period will be five years.

In accordance with section 306 of the Act and Title 21, Code of Federal Regulations (21 CFR) Part 12, by this letter you are given notice of an opportunity for a hearing to show why you should not be debarred.

If you decide to seek a hearing, you must file on or before 30 days from the date of receipt of this letter, a written request for hearing and objections. The regulations regarding a request for hearing are set forth at 21 CFR Part 12.

Page 3 - Mr. Thomas M. Rodgers, Jr.

Your failure to file a timely written request for hearing would constitute a waiver of objections concerning your debarment. If you do not request a hearing in the manner prescribed by the regulations, the agency will deny your request for a hearing and issue a final order.

A request for hearing based on mere allegations, denials, or general descriptions of positions and contentions will not be granted. Nor will a hearing be granted on issues of policy or law. To obtain a hearing, you must present specific facts showing that there is a genuine and substantial issue of fact.

The facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted of misdemeanors under Federal law as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment.

Your request for a hearing, including any material submitted in support of any objection, must be identified with Docket No. 02N-0510, and sent to: Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 1061, 5630 Fishers Lane, Rockville, Maryland, 20852. Please file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR Part 10.20(j). Publicly available submissions may be examined in the Dockets Management Branch office between 9 a.m. and 4 p.m., Monday through Friday.

Sincerely,



Kathryn C. Zoon, Ph.D.

Director

Center for Biologics Evaluation and  
Research

**SENDER: COMPLETE THIS SECTION**

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

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

2. Article Number (Copy from service label)

**COMPLETE THIS SECTION ON DELIVERY**

A. Received by (Please Print Clearly) B. Date of Delivery

C. Signature

X

Agent  
 Addressee

D. Is delivery address different from item 1?

If YES, enter delivery address below:  Yes

No

3. Service Type

Certified Mail  Express Mail  
 Registered  Return Receipt for Merchandise  
 Insured Mail  C.O.D.

4. Restricted Delivery? (Extra Fee)

Yes

7099 3400 0005 9153 6940