Task	Hourly rate	Burden hours	Labor cost
Determine care instructions	$20.00	709,500	$14,190,000
Draft and order labels	13.00	33,000	429,000
Attach labels	[8] 3.00	5,311,100	15,933,300
Total			30,552,300

Staff [8] believes that there are no current start-up costs or other capital costs associated with the Rule. Because the labeling of textile products has been an integral part of the manufacturing process for decades, manufacturers have in place the capital equipment necessary to comply with the Rule's labeling requirements. Based on knowledge of the industry, staff believes that much of the information required by the Rule would be included on the product label even absent those requirements.

John D. Graubert,

Acting General Counsel.

[FR Doc. 02–28160 Filed 11–5–02; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1526]

Robert A. Fiddes; 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. Robert A. Fiddes for 20 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. Fiddes was convicted of a felony under Federal law for conspiring to make false statements to a government agency, and was a material participant in offenses for which three other people are being debarred. Dr. Fiddes has failed to request a hearing and, therefore, has waived his opportunity for a hearing concerning this action.

DATES: This order is effective November 6, 2002.

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.

[8] See note 3.

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 September 30, 1997, the U.S. District Court for the Central District of California accepted Dr. Fiddes' plea and entered judgment against him for one count of conspiring to make false statements to a government agency, the FDA, in violation of 18 U.S.C. 371 and 1001. This conspiracy conviction was based on Dr. Fiddes participating in, directing, and encouraging the submission of false information to sponsors in required reports for clinical studies used by FDA to evaluate the safety and effectiveness of drug products.

As a result of this conviction, FDA served Dr. Fiddes by certified mail on June 6, 2002, a notice proposing to debar him for 20 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Dr. Fiddes an opportunity for a hearing on the proposal. The debarment proposal was based on findings: (1) Under section 306(b)(2)(B)(i)(II) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II)) that Dr. Fiddes was convicted of a felony under Federal law for conspiracy to make false statements to a government agency and, (2) under section 306(b)(2)(B)(iii) of the act that Dr. Fiddes was a material participant in offenses leading to the conviction and debarment of three other individuals. Dr. Fiddes was provided 30 days to file objections and to request a hearing. Dr. Fiddes 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 5.99), finds that Dr. Robert A. Fiddes: (1) Has been convicted of a felony under Federal law for conspiring to make false statements to a government agency, and (2) was a material participant in offenses leading to the conviction and debarment of three other individuals.

As a result of the foregoing findings, Dr. Robert A. Fiddes is debarred for 20 years (4 periods of 5 years, to run consecutively, based on his conviction of a Federal felony and his role as a material participant in the offenses leading to the conviction and debarment of three other individuals) 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. Fiddes, in any capacity, during his period of debarment, will be subject to civil money penalties. If Dr. Fiddes, 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. Fiddes during his period of debarment.

Any application by Dr. Fiddes for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 00N–1526 and sent to the Dockets Management Branch (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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 15, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 02–28256 Filed 11–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1528]

Delfina Hernandez; 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 Ms. Delfina Hernandez 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 Ms. Hernandez was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a government agency, and that Ms. Hernandez' conduct undermined the process for the regulation of drugs. Ms. Hernandez has failed to request a hearing and, therefore, has waived her opportunity for a hearing concerning this action.

DATES: This order is effective November 6, 2002.

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: 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 22, 1997, the U.S. District Court for the Central District of California accepted Ms. Hernandez' plea of guilty to one count of conspiring to make false statements in matters within the jurisdiction of a government agency, FDA, a Federal felony offense under 18 U.S.C. sections 371 and 1001. This conviction was based on Ms. Hernandez' participation in falsifying data and information on clinical studies for use by FDA in determining the safety and effectiveness of drug products.

As a result of this conviction, FDA served Ms. Hernandez by certified mail on May 13, 2002, a notice proposing to debar her for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. The proposal also offered Ms. Hernandez an opportunity for a hearing on the proposal. The debarment proposal was based on a finding, under section 306(b)(2)(B)(i)(II) and (a)(2) of the act (21 U.S.C. 335a(b)(2)(B)(i)(II) and (a)(2)) that Ms. Hernandez was convicted of a felony under Federal law for conspiring to make false statements in matters within the jurisdiction of a government agency, FDA, and that Ms. Hernandez' conduct undermined the process for the regulation of drugs. Ms. Hernandez was provided 30 days to file objections and to request a hearing. Ms. Hernandez did not request a hearing. Her failure to request a hearing constitutes a waiver of her opportunity for a hearing and a waiver of any contentions concerning her debarment.

II. Findings and Order

Therefore, the Director, Center for Drug Evaluation and Research, under section 306(b)(2) of the act, and under authority delegated to her (21 CFR 5.99), finds that Ms. Delfina Hernandez has been convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of drug products and that Ms. Hernandez' conduct undermined the process for the regulation of drugs.

As a result of the foregoing finding, Ms. Delfina Hernandez is debarred for 5 years 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 Ms. Hernandez, in any capacity during her period of debarment, will be subject to civil money penalties. If Ms. Hernandez, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she 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 Ms. Hernandez during her period of debarment.

Any application by Ms. Hernandez for termination of debarment under section 306(d)(4) of the act should be identified with Docket No. 00N–1528 and sent to the Dockets Management Branch (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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 15, 2002.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 02–28255 Filed 11–5–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 02M–0250, 02M–0203, 02M–0180, 02M–0218, 02M–0272, 02M–0271, 02M–0145, 02M–0311, 02M–0172, 02M–0217, 02M–0179, 02M–0255, 02M–0173, 02M–0235, 02M–0167, 02M–0174, 02M–0216, and 02M–0236]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Thinh Nguyen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In January 1998, FDA revised 21 CFR 814.44(d) and 814.45(d) (63 FR 4571, January 30, 1998) to discontinue individual publication of PMA approvals and denials in the **Federal Register**, providing instead to post this information to FDA's home page at