TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	No. of record-keepers	No. of records per record-keeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
TOTAL					422,207

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The medical device labeling regulations also refer to currently approved collections of information found in FDA regulations. The collections of information under § 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231; and the collections of information under § 801.435(g) have been approved under OMB control number 0910–0073.

Further, FDA concludes that labeling statements under §§ 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1), 801.433, 801.437(d) through (g), and 809.30(d)(2), (d)(3), and (e) do not constitute a ''collection of information'' under the PRA. Rather, these labeling statements are ''public disclosure'' of information originally supplied by the Federal Government to the recipient for the purpose of ''disclosure to the public'' (5 CFR 1320.3(c)(2)).

Reporting

These estimates are based on FDA's registration and listing database for medical device establishments and FDA's knowledge of and experience with device labeling.

Recordkeeping

These estimates are based on FDA's registration and listing database for medical device establishments, Agency communications with industry, and FDA's knowledge of and experience with device labeling.

The medical device labeling regulations also refer to previously approved collections of information. The collections of information under § 800.12(d) and 801.437(i) have been approved under OMB control number 0910–0183; and the collections of information under § 800.12(e) have been approved under OMB control number 0910–0231.

The information collection requirements under § 801.63, 801.405(b)(2) and (b)(3), 801.420(c)(2) and (c)(3), 801.430(c) and (e)(1), 801.433, 801.437(d) through (g), and 809.30(d)(2), (d)(3), and (e) are not considered information collection because the public information is originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)).

Dated: August 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–20098 Filed 8–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0064]

Ray Nathan; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Ray Nathan's request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) permanently debarring Nathan 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 Nathan was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. Nathan has failed to file with the Agency information and analysis sufficient to create a basis for a hearing concerning this action.

DATES: This order is effective August 9, 2011.

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: G. Matthew Warren, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4210, Silver Spring, MD 20993, 301–796–4613.

SUPPLEMENTARY INFORMATION:

I. Background

On May 3, 2007, the U.S. District Court for the District of Massachusetts entered a criminal judgment against Nathan pursuant to his guilty plea for wire fraud under 18 U.S.C. 1343 and 1342. The basis for this conviction was Nathan's scheme to obtain from Lyne Laboratories (Lyne) a copy of a certificate of analysis for the drug PhosLo to determine how to manufacture a generic version of the drug. Nathan, a founder of a startup drug company named Argus Therapeutics (Argus), admitted that he created a fake email account for a senior employee at Nabi Biopharmaceuticals (Nabi), a Florida company. In an effort to obtain the certificate of analysis, he then sent an email from that account to an employee at Lyne, which manufactured PhosLo as a subcontractor for Nabi. When the Lyne employee requested a physical address to which the certificate should be sent, Nathan provided the address of another principal at Argus via email. Nathan subsequently sent a third email from the fraudulent email account to inquire about the status of his request.

Nathan is subject to debarment based on a finding, under section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)), that he was convicted of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of any drug product. By a letter dated March 2, 2010, FDA served Nathan a notice proposing to permanently debar him from providing services in any capacity to a person having an approved or pending drug product application. In a letter dated April 6, 2010, Nathan requested a hearing on the proposal, and he submitted materials in support of that request on May 10, 2010. In his request for a hearing, Nathan acknowledges his conviction for wire fraud under Federal law, as alleged by FDA. However, he argues that the conduct underlying the conviction does not relate to the development or approval, including the

process for development or approval, of any drug product or otherwise relate to the regulation of drugs under the FD&C Act.

We reviewed Nathan's request for a hearing, as well as the materials submitted in support of that request, and find that Nathan has not created a basis for a hearing because hearings will be granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (see 21 CFR 12.24(b)).

The Chief Scientist and Deputy Commissioner for Science and Public Health has considered Nathan's arguments and concludes that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Argument

In support of his hearing request, Nathan argues that the conduct underlying his conviction for wire fraud does not relate to the development or approval of a drug product or otherwise relate to the regulation of drugs under the FD&C Act. We need not address whether the conduct relates to the regulation of drugs under the FD&C Act because it clearly relates to the development of a drug product. Nathan argues that the ''development or approval'' of a drug product subject to FDA's premarket review begins with preclinical testing in animals and ends with postmarket studies. He contends that his actions in attempting to obtain a certificate of analysis for PhosLo do not relate to that process but instead relate to ''pre-development'' market research. Nathan maintains that he and Argus were attempting to evaluate production costs for a generic version of PhosLo and that Argus did not possess the funding necessary to pursue the steps that he asserts are associated with the actual development or approval of a drug product.

Nathan's narrow reading of section 306(a)(2)(A) is not convincing. In analyzing the scope of a statute, the first step is to ''determine whether the language at issue has a plain and unambiguous meaning.'' (*Robinson* v. *Shell Oil Co.,* 519 U.S. 337, 340 (1997)) Statutory interpretation turns on ''the language itself, the specific context in which that language is used, and the broader context of the statute as a whole'' (*id.* at 341). Here, as FDA has held in denying a hearing in a debarment proceeding in the past, ''[t]he statutory language, 'relating to the development or approval * * *,' by definition encompasses all things that are logically connected to the development or approval of a drug product.'' (59 FR 62399, December 5, 1994) As defined by ''Merriam-Webster's Collegiate Dictionary,'' ''develop'' means, inter alia, ''to explore the possibilities of'' and ''to make suitable for commercial * * * purposes.'' (see ''Merriam-Webster's Collegiate Dictionary,'' 10th Edition (2002)). Although Nathan argues that researching manufacturing techniques and the commercial viability of those techniques is not part of the drug development process, it is clearly a necessary step in that process. At the very least, such research relates to that development process for a drug product. Indeed, the information that Nathan attempted to obtain through his illegal conduct would have enabled Argus to begin compiling the chemistry, manufacturing, and controls section for an abbreviated new drug application (see 21 CFR 314.94(a)(9), 314.50(d)(1)). Debarring individuals who have been convicted of a felony for attempting to obtain such key information through fraudulent means is consistent with the clear remedial goals of section 306 of the FD&C Act.

III. Findings And Order

Therefore, the Chief Scientist and Deputy Commissioner for Science and Public Health, under section 306(a)(2)(A) of the FD&C Act and under authority delegated to him, finds that Nathan has been convicted a of a felony under Federal law for conduct relating to the development or approval, including the process for development or approval, of a drug product.

As a result of the foregoing findings, Nathan is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C 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 August 9, 2011 (21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(ii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application who knowingly uses the services of Nathan, in any capacity during his period of debarment, will be subject to civil money penalties. If Nathan, 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 Nathan during his period of debarment.

Any application by Nathan for termination of debarment under section 306(d) of the FD&C Act (21 U.S.C. 335a(d)) should be identified with Docket No. FDA–2010–N–0064 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: *July 7, 2011.*

Jesse L. Goodman,

Chief Scientist and Deputy Commissioner for Science and Public Health.

[FR Doc. 2011–20181 Filed 8–8–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0428]

Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays.'' This guidance document describes a means by which the herpes simplex virus types 1 and 2 serological assay device type may comply with the requirement of special controls for class II devices.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–