for leaders of Tribal Governments operating Head Start and Early Head Start programs in Region X and in Alaska. The Consultation Session for Region X will take place Monday, October 17, 2011, in Seattle, Washington. The Consultation Session for the State of Alaska will take place Wednesday, October 19, 2011, in Anchorage, Alaska, immediately preceding the annual Alaska Federation of Natives convention. We are convening the OHS Tribal Consultations in conjunction with other Tribal Leader events in order to minimize the financial and travel burden for participants.

The agendas for both scheduled OHS Tribal Consultations will be organized around the statutory purposes of Head Start Tribal Consultations related to meeting the needs of American Indian and Alaska Native children and families, taking into consideration funding allocations, distribution formulas, and other issues affecting the delivery of Head Start services in their geographic locations. In addition, OHS will share actions taken and in progress to address the issues and concerns raised in 2010 OHS Tribal Consultations.

Tribal leaders and designated representatives interested in submitting written testimony or proposing specific agenda topics for the Seattle or Anchorage Consultation Sessions should contact Camille Loya at *Camille.Loya@acf.hhs.gov* at least three days in advance of the Session. Proposals should include a brief description of the topic area along with the name and contact information of the suggested presenter.

The Consultation Sessions will be conducted with elected or appointed leaders of Tribal Governments and their designated representatives [42 U.S.C.9835, Section 640(l)(4)(A)]. Designees must have a letter from the Tribal Government authorizing them to represent the Tribe. The letter should be submitted at least three days in advance of the Consultation Session to Camille Loya at (202) 205–9721 (fax). Other representatives of Tribal organizations and Native nonprofit organizations are welcome to attend as observers.

A detailed report of each Consultation Session will be prepared and made available within 90 days of the Consultation Session to all Tribal Governments receiving funds for Head Start and Early Head Start programs. Tribes wishing to submit written testimony for the report should send testimony to Camille Loya at *Camille.Loya@acf.hhs.gov* either prior to the Consultation Session or within 30 days after the meeting.

Oral testimony and comments from the Consultation Session will be summarized in the report without attribution, along with topics of concern and recommendations. Hotel and logistical information for all Consultation Sessions has been sent to Tribal leaders via e-mail and posted on the Head Start Resource Center Web site at *http://www.headstartresourcecenter.org.*

Dated: August 1, 2011.

Yvette Sanchez Fuentes,

Director, Office of Head Start.

[FR Doc. 2011–20071 Filed 8–8–11; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0116]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 8, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0485. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Device Labeling Regulations—(OMB Control Number 0910–0485)—(Extension)

Section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded and subject to a regulatory action. Certain provisions under section 502 require manufacturers, importers, and distributors of medical devices to disclose information about themselves or the devices, on the labels or labeling for the devices.

Section 502(b) of the FD&C Act requires that for packaged devices, the label must bear the name and place of business of the manufacturer, packer, or distributor as well as an accurate statement of the quantity of the contents. Section 502(f) of the FD&C Act requires that the labeling for a device must contain adequate directions for use. FDA may however, grant an exemption, if the Agency determines that the adequate directions for use labeling requirements are not necessary for the particular case, as it relates to protection of the public health.

FDA regulations under parts 800, 801, and 809 (21 CFR parts 800, 801, and 809) require disclosure of specific information by manufacturers, importers, and distributors of medical devices about themselves or the devices, on the label or labeling for the devices to health professionals and consumers. FDA issued these regulations under the authority of sections 201, 301, 502, and 701 of the FD&C Act (21 U.S.C. 321, 331, 352, and 371). Most of the regulations under parts 800, 801, and 809 are derived from requirements of section 502 of the FD&C Act, which provides in part, that a device shall be misbranded if among other things, its label or labeling fails to bear certain required information concerning the device, is false or misleading in any particular way, or fails to contain adequate directions for use.

Reporting Burden

Sections 800.10(a)(3) and 800.12(c) require that the label for contact lens cleaning solutions bear a prominent statement alerting consumers of the tamper-resistant feature. Further, § 800.12 requires that packaged contact lens cleaning solutions contain a tamper-resistant feature, to prevent malicious adulteration.

Section 800.10(b)(2) requires that the labeling for liquid ophthalmic preparations packed in multiple-dose containers provide information on the duration of use and the necessary warning information to afford adequate protection from contamination during use.

Section 801.1 requires that the label for a device in package form, contain the name and place of business of the manufacturer, packer, or distributor.

Section 801.5 requires that labeling for a device include information on intended use as defined under § 801.4 and provide adequate directions to assure safe use by the lay consumers.

Section 801.61 requires that the principal display panel of an over-the-counter (OTC) device in package form must bear a statement of the identity of the device. The statement of identity of the device must include the common name of the device followed by an accurate statement of the principal intended actions of the device.

Section 801.62 requires that the label for an OTC device in package form must bear a statement of declaration of the net quantity of contents. The label must express the net quantity in terms of weight, measure, numerical count, or a combination of numerical count and weight, measure, or size.

Section 801.109 establishes labeling requirements for prescription devices, in which the label for the device must describe the application or use of the device, and contain a cautionary statement restricting the device for sale by, or on the order of an appropriate professional.

For prescription by a licensed practitioner, § 801.110 establishes labeling requirements for a prescription device delivered to the ultimate purchaser or user. The device must be accompanied by labeling bearing the name and address of the licensed practitioner, directions for use, and cautionary statements if any, provided by the order.

Section 801.150(e) requires a written agreement between firms involved when a nonsterile device is assembled or packaged with labeling that identifies the final finished device as sterile, for which the device is ultimately introduced into interstate commerce to an establishment or contract manufacturer to be sterilized. When a written agreement complies with the requirements under § 801.150(e), FDA takes no regulatory action against the device as being misbranded or adulterated. In addition, § 801.150(e) requires that each pallet, carton, or other designated unit, be conspicuously marked to show its nonsterile nature when introduced into interstate commerce, and while being held prior to sterilization.

Section 801.405(b)(1) provides for labeling requirements for articles, including repair kits, re-liners, pads, and cushions, intended for use in temporary repairs and refitting of dentures for lay persons. Section 801.405(b)(1) also requires that the labeling contain the word ''emergency'' preceding and modifying each indication-for-use statement for denture repair kits and the word ''temporary'' preceding and modifying each indication-for-use statement for re-liners, pads, and cushions.

Section 801.405(c) provides for labeling requirements that contain essentially the same information described under § 801.405(b)(1). The information is intended to enable a lay person to understand the limitations of using OTC denture repair kits, and denture re-liners, pads, and cushions.

Section 801.420(c)(1) requires that manufacturers or distributors of hearing aids develop a user instructional brochure to be provided by the dispenser of the hearing aid to prospective users. The brochure must contain detailed information on the use and maintenance of the hearing aid.

Section 801.420(c)(4) establishes requirements that the user instructional brochure or separate labeling, provide for technical data elements useful for selecting, fitting, and checking the performance of a hearing aid. In addition, § 801.420(c)(4) provides for testing requirements to determine that the required data elements must be conducted in accordance with the American National Standards Institute's (ANSI) ''Specification of Hearing Aid Characteristics,'' ANSI S3.22–1996 (ASA 70–1996); (Revision of ANSI S3.22–1987), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

Section 801.421(b) establishes requirements for the hearing aid dispenser to provide prospective users with a copy of the user instructional brochure along with an opportunity to review comments, either orally or by the predominant method of communication used during the sale.

Section 801.421(c) establishes requirements for the hearing aid dispenser to provide a copy of the user instructional brochure to the prospective purchaser of any hearing aid upon request or, if the brochure is unavailable, provide the name and address of the manufacturer or distributor from which it may be obtained.

Section 801.430(d) establishes labeling requirements for menstrual tampons to provide information on signs, risk factors, and ways to reduce the risk of Toxic Shock Syndrome (TSS).

Section 801.430(e)(2) requires menstrual tampon package labels to provide information on the absorbency term based on testing required under § 801.430(f) and an explanation of selecting absorbencies that reduce the risk of contracting TSS.

Section 801.430(f) establishes requirements that manufacturers of menstrual tampons devise and follow an ongoing sampling plan for measuring the absorbency of menstrual tampons. Further, manufacturers must use the method and testing parameters described under § 801.430(f).

Section 801.435(b), (c), and (h) establishes requirements for condom labeling to bear an expiration date that is supported by testing that demonstrates the integrity of three random lots of the product.

Section 809.10(a) and (b) establishes requirements that a label for an in vitro diagnostic device and the accompanying labeling (package insert), must contain information identifying its intended use, instructions for use and lot or control number, and source.

Section 809.10(d)(1) provides that the labeling requirements for general purpose laboratory reagents may be exempt from the requirements of § 809.10(a) and (b), if the labeling contains information identifying its intended use, instructions for use, lot or control number, and source.

Section 809.10(e) provides that the labeling for ''Analytic Specific Reagents'' (ASRs) must provide information identifying the quantity or proportion of each reagent ingredient, instructions for use, lot or control number, and source.

Section 809.10(f) provides that the labeling for OTC test sample collection systems for drugs of abuse must include information on the intended use, specimen collection instructions, identification system, and information about use of the test results. In addition, § 809.10(f) requires that this information be in language appropriate for the intended users.

Section 809.30(d) requires that advertising and promotional materials for ASRs include the identity and purity of the ASR and the identity of the analyte.

Section 1040.20(d) provides that manufacturers of sunlamp products and ultraviolet lamps are subject to the labeling regulations under part 801.

Recordkeeping Burden

Section 801.150(a)(2) establishes recordkeeping requirements for reprocessors, relabelers, or repackagers to retain a copy of the agreement containing the specifications for the processing, labeling, or repacking of the device for 2 years after the shipment or delivery of the device. Section 801.150(a)(2) also requires that the subject respondents make copies of this agreement available for inspection at any reasonable hour to any officer or employee of the Department of Health and Human Services (HHS), upon their request.

Section 801.421(d) establishes requirements for hearing aid dispensers to retain copies of all physician statements or any waivers of medical evaluation for 3 years after dispensing the hearing aid.

Section 801.410(e) requires copies of invoices, shipping documents, and records of sale or distribution of all impact resistant lenses, including finished eyeglasses and sunglasses, be maintained for 3 years by the retailer and made available upon request by any officer or employee of FDA or by any other officer or employee acting on behalf of the Secretary of HHS.

Section 801.410(f) requires that the results of impact tests and description of the test method and apparatus be retained for a period of 3 years.

Section 801.421(d) requires hearing aid dispensers to retain a copy of any written statement from a physician required under § 801.421(a)(1), or any written statement waiving medical evaluation required under § 801.421(a)(2)(iii) for 3 years after the dispensing of the hearing aid.

Section 801.435(g) requires latex condom manufacturers to document and provide, upon request, an appropriate justification for the application of the testing data from one product on any variation of that product to support expiration dating in the user labeling.

In the **Federal Register** of March 14, 2011 (76 FR 13623), FDA published a 60-day notice requesting public comment on the proposed collection of information. In response to that notice, one comment was received. The comment questioned the accuracy of FDA's estimate of the number of respondents reporting under 21 CFR 1040.20(d) regarding sunlamp labeling requirements. Specifically, the comment suggested that the Agency provided a low estimate, however the comment did not provide a basis by which FDA may make an alternative estimate. FDA based its estimate on the number of sunlamp manufacturers currently registered in FDA's Uniform Registration and Listing System (FURLS) database.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	No. of respondents	No. of responses per respondent	Total annual responses	Average burden per response (in hours)	Total hours
800.10(a)(3) and 800.12(c)	37	100	3,700	1	3,700
800.10(b)(2)	37	100	3,700	1	3,700
801.1	23,393	6	140,358	.1	140,036
801.5	5,000	3.5	17,500	22.35	391,125
801.61	5,000	3.5	17,500	1	17,500
801.62	1,000	5	5,000	1	5,000
801.109	18,000	3.5	63,000	17.77	1,119,510
801.110	10,000	50	500,000	0.25	125000
801.150(e)	90	20	1,800	4	7,200
801.405(b)(1)	99	1.7	168	4	673
801.405(c)	99	1.7	168	4	673
801.420(c)(1)	275	5	1,375	40	55,000
801.420(c)(4)	275	5	1,375	80	110,000
801.421(b)	10,000	160	1,600,000	0.30	480,000
801.421(c)	10,000	5	50,000	0.17	8,500
801.430(d)	45	2	90	2	180
801.430(e)(2)	45	2	90	2	180
801.430(f)	45	2	90	80	7,200
801.435(b), (c), and (h)	86	3.4	292	100	29,200
809.10(a) and (b)	1,700	6	10,200	80	816,000
809.10(d)(1)	300	2	600	40	24,000
809.10(e)	300	25	7,500	1	7,500
809.10(f)	20	1	20	100	2,000
809.30(d)	300	25	7,500	1	7,500
1040.20(d)	110	1	110	10	1,100
TOTAL	.....	.....	.....	.....	3,362,477

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

TABLE 2—ESTIMATED AVERAGE ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	No. of record-keepers	No. of records per record-keeper	Total annual records	Average burden per recordkeeping (in hours)	Total hours
801.150(a)(2)	57	1	57	0.50	29
801.410(e) and (f)	1,136	924,100	27,723,000	0.0008	22,178
801.421(d)	10,000	160	1,600,000	0.25	400,000

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