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–

0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Haja Sittana El Mubarak, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5519, Silver Spring, MD 20993–0002, 301–796–6193.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations on the types of information and data that FDA believes needs to be included in a 510(k) for herpes simplex virus (HSV) types 1 and 2 serological assays. HSV serological assays are devices that consist of antigens and antisera used in various serological tests to identify antibodies to HSV in serum. Additionally, some of the assays consist of HSV antisera conjugated with a fluorescent dye (immunofluorescent assays) used to identify HSV directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by HSVs and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from a mild infection to a severe generalized disease with a fatal outcome. We revised the existing guidance by rewriting the method comparison section and the sample selection inclusion and exclusion criteria section. The revisions define and differentiate the required studies and the study populations for the assessment of the safety and effectiveness of the different types of HSV types 1 and 2 serological assays. Additionally, the revisions include several corrections and clarifications throughout the document to ensure accuracy, consistency, and ease of reading. The draft of this guidance issued on September 28, 2010 (75 FR 59726) and the comment period closed on December 27, 2010. We received no comments on the draft guidance. Elsewhere in this issue of the **Federal Register**, FDA is finalizing the amendment of the special controls guidance document and designating this guidance as the class II special control for HSV types 1 and 2 serological assays. Following the effective date in the final rule finalizing the amendment of the special controls guidance document, this revised guidance document will serve as the special control for this device and supersedes the guidance with the same name that issued on April 3, 2007 (72 FR 15888).

II. Significance of Special Controls Guidance Document

FDA believes that adherence to the recommendations described in this guidance document, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the HSV types 1 and 2 serological assays classified under 21 CFR 866.3305. In order to be classified as a class II device, HSV types 1 and 2 serological assays must comply with the requirements of special controls; manufacturers must address the issues requiring special controls as identified in the guidance document, either by following the recommendations in the guidance document or by some other means that provides equivalent assurances of safety and effectiveness.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* To receive ''Class II Special Controls Guidance Document: Herpes Simplex Virus Types 1 and 2 Serological Assays,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1713 to identify the guidance you are requesting.

IV. Paperwork Reduction Act

This guidance refers to previously approved collections of information found in FDA regulations and guidance documents. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; and the collections of information in 21 CFR part 801 and 21 CFR 809.10 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 3, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20117 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–2011–N–0002]

Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Immunology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 14, 2011, from 8 a.m. to 6 p.m.

Location: Hilton Washington DC North/Gaithersburg, salons A, B, and C, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6639, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and