citizen petition dated November 9, 2010 (Docket No. FDA–2010–P–0577), under 21 CFR 10.30, requesting that the Agency determine whether NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records, FDA has determined under 314.161 that NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, were not withdrawn for reasons of safety or effectiveness. The petitioners have identified no data or other information suggesting that NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, were withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to NUVIGIL (armodafinil) Tablets, 100 mg and 200 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 18 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–18473 Filed 7–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0487]

Draft Guidance for Industry: Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma'' dated July 2011. The draft guidance document recognizes the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 1.0.1 dated December 2010, as an acceptable mechanism that is consistent with FDA's requirements and recommendations for collecting Source Plasma donor history information. The Plasma Protein Therapeutics Association (PPTA) Source Plasma donor history questionnaires and accompanying materials (SPDHQ documents) will provide blood establishments that collect Source Plasma with a specific process for administering questions to Source Plasma donors to determine their eligibility to donate.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 20, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft 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.

FOR FURTHER INFORMATION CONTACT: Tami Belouin, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Guidance for Industry: Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma'' dated July 2011. The draft guidance document recognizes the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 1.0.1 dated December 2010, prepared by the PPTA, as an acceptable mechanism that is consistent with FDA's requirements and recommendations for collecting Source Plasma donor history information. The SPDHQ documents will provide blood establishments that collect Source Plasma with a specific process for administering questions to Source Plasma donors to determine their eligibility to donate. The guidance also advises Source Plasma manufacturers who choose to implement the acceptable SPDHQ documents on how to report the manufacturing change consisting of the implementation of the SPDHQ under 21 CFR 601.12.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. 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 601.12 have been approved under OMB Control No. 0910–0338; 21 CFR 640.63 have been approved under OMB Control No. 0910–0116.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: July 18 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–18472 Filed 7–21–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0381]

Generic Drug User Fee; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting to provide a public update and to gather additional stakeholder input on the development of a generic drug user fee program. A user fee program could provide necessary supplemental funding, in addition to current Congressional appropriations, to facilitate the timely review of human generic drug applications by FDA. FDA has been in negotiations with the regulated industry aimed at providing a consensus proposal for Congressional consideration. In the interest of transparency, and to assure that all interested stakeholders' views are heard and considered, whether they are present at the negotiations or not, FDA is holding a fourth public meeting on this topic to provide an update and to gather additional input on such a program.

Date and Time: The public meeting will be held on August 25, 2011, from 2 to 3:30 p.m.

Location: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 1, Conference Rooms 4101, 4103, and 4105, Silver Spring, MD 20993–0002.

Contact Person: Mari Long, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4237, Silver Spring, MD 20993–0002, 301–796–7574, FAX 301–847–3541, *mari.long@fda.hhs.gov;* or

Peter C. Beckerman, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 4238, Silver Spring, MD 20993–0002, 301–796–4830, FAX 301–847–3541, *peter.beckerman@fda.hhs.gov.*

Registration and Requests for Oral Presentations: If you wish to attend and/or present at the meeting, please e-mail your registration information to *GDUFA_Meeting3@fda.hhs.gov* by August 18, 2011. Your e-mail should contain complete contact information for each attendee, including name, title, affiliation, address, e-mail address, and telephone number. Registration is free and will be on a first-come, first-served basis. Early registration is recommended because seating is limited. FDA may limit the number of participants from each organization as well as the total number of participants, based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. We will try to accommodate all persons who wish to make a presentation. The time allotted for presentations may depend on the number of persons who wish to speak, and if the entire meeting time is not needed for presentations, FDA reserves the right to terminate the meeting early.

If you need special accommodations because of disability, please contact Mari Long or Peter Beckerman (see *Contact Person*) at least 7 days before the meeting.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic or written comments regarding this document. To ensure consideration, all comments must be received by September 26, 2011. Submission of comments prior to the meeting is strongly encouraged. Submit any comments that you plan to present at the public meeting to the docket by the date of the public meeting, but note that either electronic or written comments generally may be submitted until September 26, 2011.

Submit electronic comments 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. 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.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing its intention to hold a public meeting related to generic drug user fees. New legislation would be required for FDA to establish and collect user fees for generic drugs, and FDA has been engaged in negotiations with industry over aspects of a joint proposal for a generic drug user fee program, including fees and performance goals, for several months. The Agency has held three prior public meetings on the topic before and during this process. Because FDA can only negotiate with trade organizations, not individual companies, but remains interested in hearing from non-affiliated companies in addition to patient and consumer stakeholders, the Agency is holding an additional public meeting. The meeting will provide a status update and seek input from stakeholders on generic drug user fees. In addition, FDA continues to encourage all interested stakeholders to submit either electronic or written comments to the docket (see *Comments*).

II. What information should you know about the public meeting, when and where will the public meeting occur, and what format will FDA use?

Through this notice, we are announcing a public meeting to update stakeholders and hear stakeholder views on what features FDA should propose for a generic drug user fee program. We will conduct the meeting on August 25, 2011, from 2 to 3:30 p.m. at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 1, Conference Rooms 4101, 4103, and 4105, Silver Spring, MD 20993–0002. In general, the