document). We base this estimate on our experience with related contingency planning under the draft guidance for industry entitled: ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products'' (Absenteeism Draft Guidance) published in the **Federal Register** of January 8, 2010 (75 FR 1060), and October 18, 2010 (75 FR 63832), and the public comments we received on our burden estimate for that guidance. The Absenteeism Draft Guidance recommends that drug and biological product manufacturers develop written plans to maintain an adequate supply of medically necessary products during an emergency that results in high employee absenteeism. Although the draft guidance that is the subject of this **Federal Register** document is not related to employee absenteeism, the two guidance documents apply to a similar group of manufacturers and we believe the contingency plans recommended in both draft guidance documents will include similar elements. Accordingly, we believe the burden estimates from the Absenteeism Draft are relevant to this draft guidance. However, we specifically request comment on these contingency plan burden hour estimates.

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

TABLE 1—ESTIMATED REPORTING BURDEN [1]

	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
Voluntary Reporting Under Section IV of the Draft Guidance	480	1	480	2	960
Total					960

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

	Number of recordkeepers	Number of records per recordkeeper	Total records	Average burden per recordkeeping (in hours)	Total hours
Voluntary Contingency Plans Under Section VI of the Draft Guidance	70	1	70	500	35,000
Total					35,000

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

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either written or electronic comments regarding this document. It is only necessary to send one set of 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.

V. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm121568.htm, http://www.fda.gov/cber/guidelines.htm,* or *http://www.regulations.gov.*

Dated: February 22, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4439 Filed 2–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0080]

Draft Guidance on Food and Drug Administration Oversight of Positron Emission Tomography Drug Products—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''FDA Oversight of PET Drug Products—Questions and Answers.'' The draft guidance provides questions and answers that address nearly all aspects of the FDA approval and surveillance processes, including application submission, review, compliance with good manufacturing practices, inspections, registration and listing, and user fees.

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 May 29, 2012.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. 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: Elizabeth Giaquinto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 6164,

Silver Spring, MD 20993–0002, 301–796–3416.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''FDA Oversight of PET Drug Products—Questions and Answers.'' In 1997, Congress passed the Food and Drug Administration Modernization Act (the Modernization Act) (Pub. L. 105–115). Section 121 of the Modernization Act directed FDA to establish appropriate approval procedures and current good manufacturing practices (CGMP) for PET drugs. The procedures were finalized and an implementation timeline was instituted on December 10, 2009, when FDA published regulations that described the minimum CGMP standards that each PET drug manufacturer is to follow during the production of a PET drug (see part 212 (21 CFR part 212)).[1] Under the requirements of section 121 of the Modernization Act, within 2 years following that publication date, a new drug application (NDA) or abbreviated new drug application (ANDA) must be submitted for any PET drug marketed for clinical use in the United States.

Recognizing that many PET drug producers are unfamiliar with the drug approval process, FDA issued the guidance entitled PET Drug Applications—Content and Format for NDAs and ANDAs,[2] and held a public meeting in March 2011 to assist applicants in preparing NDAs and ANDAs for the three most commonly used PET drugs. Numerous questions have been raised since that public meeting on all aspects of FDA oversight of PET drugs. This draft guidance is being issued to respond to the questions that have been submitted to date, and it will be revised periodically to respond to additional questions that have been submitted and are expected to be submitted in the future.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the FDA oversight of PET drugs. 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 requirements of the applicable statutes and regulations.

II. 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. 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.

III. 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 part 314 were approved under OMB control numbers 0910–0001 and 0910–0338; the collections of information in 21 CFR part 312 were approved under OMB control number 0910–0014; the collections of information in part 212 were approved under OMB control number 0910–0667; the collections of information in 21 CFR parts 210 and 211 were approved under 0910–0139; and the collections of information in 21 CFR part 207 were approved under OMB control number 0910–0445. The draft guidance also refers to collections of information associated with submitting Form FDA 3397 (Prescription Drug User Fee Cover Sheet), approved under OMB control number 0910–0297.

IV. Electronic Access

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

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4427 Filed 2–24–12; 8:45 am]

BILLING CODE 4160–01–P

[1] The regulation, CGMP guidance, and supportive information, including historical documents, are available at *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm.*

[2] We update guidances periodically. To make sure you have the most recent version of a guidance, check FDA's Drugs guidance Web page at: *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0621]

Final Decision on Withdrawal of Breast Cancer Indication for AVASTIN (Bevacizumab) Following Public Hearing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final decision withdrawing approval of the breast cancer indication for AVASTIN (Bevacizumab). The Commissioner of Food and Drugs (the Commissioner) issued the decision following a June 2011 public hearing on a proposal to withdraw the approval.

DATES: Withdrawal of AVASTIN's breast cancer indication was effective November 18, 2011.

ADDRESSES: Submit written requests for single copies of the decision to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. The final decision, hearing transcript, and other documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1601, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the decision and related documents.

FOR FURTHER INFORMATION CONTACT: Sharon Sickafuse, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–2320.

SUPPLEMENTARY INFORMATION:

I. Background

On February 22, 2008, FDA's Center for Drug Evaluation and Research (CDER) approved a supplemental biologics license application (sBLA 125085/91) submitted by Genentech, Inc. (Genentech), for the use of AVASTIN in combination with paclitaxel for patients who have not received chemotherapy for treatment of HER2-negative metastatic breast cancer (MBC). This approval was issued under the Agency's accelerated approval regulations for biological products, 21 CFR part 601, subpart E. Consistent with those regulations, the approval was