TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/FDA Form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
316.10, 316.12, and 316.14	2	1	2	100	200
316.20, 316.21, and 316.26	225	2	450	150	67,500
Form FDA 3671	50	3	150	45	6,750
316.22	65	1	65	2	130
316.27	43	1	43	5	215
316.30	450	1	450	3	1,350
316.36	2	3	6	15	90
Total					76,235

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

Dated: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23846 Filed 10–6–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0222]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On July 16, 2014, the Agency submitted a proposed collection of information entitled ''Guidance for Industry on User Fee Waivers, Reductions, and Refunds for Drug and Biological Products'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0693. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23842 Filed 10–6–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0432]

Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint To Support Accelerated Approval; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' This guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pathological complete response (pCR) as a surrogate endpoint that could support approval under the accelerated approval regulations. Despite advances in systemic therapy of early-stage breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. This guidance is intended to encourage industry innovation and expedite the development of breakthrough therapies to treat high-risk early-stage breast cancer. This guidance finalizes the draft guidance issued May 30, 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, 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 guidance document.

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.

FOR FURTHER INFORMATION CONTACT: Tatiana Prowell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2112, Silver Spring, MD 20993–0002, 301–796–2330.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Pathological Complete Response in Neoadjuvant Treatment of High-Risk Early-Stage Breast Cancer: Use as an Endpoint to Support Accelerated Approval.'' Under the accelerated approval regulations (21 CFR part 314, subpart H, and 21 CFR part 601, subpart E), FDA may grant marketing approval for a new drug on the basis of adequate and well-controlled trials establishing

that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit (e.g., in early-stage breast cancer, an improvement in disease-free or overall survival), provided that the applicant conducts additional trials or collects additional data after approval to verify and describe the predicted clinical benefit. This guidance is intended to assist applicants in designing trials to support marketing approval of drugs to treat breast cancer in the neoadjuvant (preoperative) setting using pCR as a surrogate endpoint that could support approval under the accelerated approval regulations. The guidance provides acceptable definitions of pCR for regulatory purposes. The guidance also describes appropriate patient populations for inclusion in neoadjuvant trials conducted with regulatory intent. Finally, the guidance outlines critical design features of trials for both accelerated approval and confirmation of clinical benefit to support regular approval.

FDA recognizes that despite advances in adjuvant systemic therapy of breast cancer over the past few decades, there remains a significant unmet medical need for certain high-risk or poor prognosis populations of early-stage breast cancer patients. Developing highly effective new drugs for these populations is an FDA priority. In providing guidance on the use of pCR as a surrogate endpoint that could support accelerated approval in the neoadjuvant setting, FDA hopes to encourage industry innovation and expedite the development and widespread availability of highly effective novel therapies to treat high-risk early-stage breast cancer.

This guidance finalizes the draft guidance issued May 30, 2012 (77 FR 31858). The current version clarifies appropriate trial designs and development strategies to support accelerated approval in the neoadjuvant setting, defines acceptable endpoints for accelerated approval and confirmation of clinical benefit, standardizes the approach to postoperative systemic therapy, includes guidelines for evaluation of the axillary lymph nodes, and provides detailed recommendations for pathology standard operating procedures.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on use of pCR as an endpoint to support accelerated approval of drug and biological products to treat high-risk early-stage breast cancer patient populations. 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. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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 parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively. The collections of information for special protocol assessments have been approved under OMB control number 0910–0470.

III. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

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: October 1, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23845 Filed 10–6–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1208]

Laboratory Site Tours Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Tobacco Products' (CTP) Office of Science is announcing an invitation for participation in its Laboratory Site Tours Program. This program is intended to give CTP staff an opportunity to visit facilities involved in the testing and analysis of tobacco products and tobacco smoke. These visits are intended to provide CTP staff with the opportunity to gain a better understanding of tobacco science and laboratory operations and are not intended as regulatory inspections or facility visits for the purposes of developing Tobacco Product Manufacturing Practice regulations. The purpose of this notice is to invite parties interested in participating in the Laboratory Site Tours Program to submit their requests to CTP.

DATES: Submit either an electronic or written request for participation in this program by December 8, 2014. The request should include a description of your facility, including, as applicable, a list of the types of testing and analyses of tobacco products and tobacco smoke performed. Please specify the physical address(es) of the site(s) for which you are submitting a request, along with a proposed 1-day tour agenda.

ADDRESSES: If your facility is interested in offering a site visit, submit either an electronic request to *http://www.regulations.gov* or a written request to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carolyn Dresler, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, rm. G335, Silver Spring, MD 20993–0002, 240–402–4067, *carolyn.dresler@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On June 22, 2009, the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) was signed into law, amending the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and giving FDA authority to regulate tobacco product manufacturing, distribution, and marketing.

CTP's Office of Science is conducting the Laboratory Site Tours Program to provide its scientific and regulatory staff the opportunity to gain a better understanding of tobacco science and laboratory operations, to include tobacco product testing and analysis. CTP's goal for the Laboratory Site Tours Program is for its staff to gain: (1) Firsthand exposure to laboratories that perform tobacco product testing and (2)