

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Mandatory Grant Financial Report	900	4	5	18,000

Estimated Total Annual Burden Hours:

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV. Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018-03976 Filed 2-26-18; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2017-N-3203]

Wyeth Pharmaceuticals Inc. et al.; Withdrawal of Approval of 121 New Drug Applications and 161 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of June 21, 2017 (82 FR 28322). The document announced the withdrawal of approval of 121 new drug applications (NDAs) and 161

abbreviated new drug applications from multiple applicants, withdrawn as of July 21, 2017. The document indicated that FDA was withdrawing approval of NDA 204508, Clinolipid 20% (olive oil and soybean oil) USP, 16%/4%, after receiving a request from the NDA holder, Baxter Healthcare Corp. (Baxter), 32650 N Wilson Rd., Round Lake, IL 60073. Before the approval of NDA 204508 was withdrawn, Baxter informed FDA that it did not want the approval of this NDA withdrawn. Because Baxter timely requested that approval of this NDA not be withdrawn, the approval of NDA 204508 is still in effect.

FOR FURTHER INFORMATION CONTACT:

Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993-0002, 301-796-3601.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Wednesday, June 21, 2017, appearing on page 28322 in FR Doc. 2017-12908, the following correction is made:

On page 28329, in table 1, the entry for NDA 204508 is removed.

Dated: February 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-03925 Filed 2-26-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. FDA-2018-N-0663]

Tissue Agnostic Therapies in Oncology: Regulatory Considerations for Orphan Drug Designation; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the following public workshop entitled “Tissue Agnostic Therapies in Oncology: Regulatory

Considerations for Orphan Drug Designation.” The purpose of the public workshop is to discuss factors FDA should consider when evaluating drugs for orphan designation that treat a tissue agnostic disease or condition in oncology, and additional factors related to orphan exclusivity FDA should consider when approving a product with a tissue agnostic indication.

DATES: The public workshop will be held on May 9, 2018, from 9 a.m. to 5 p.m. The public workshop may be extended or may end early depending on the level of public participation. Submit either electronic or written comments on this public workshop by June 8, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503, Section A), Silver Spring, MD 20993-0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 8, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of June 8, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are