

5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) are currently listed in the “Discontinued Drug Product List” section of the Orange Book. In the **Federal Register** of October 13, 2015 (80 FR 61426), FDA announced that it was withdrawing approval of NDAs 017390 and 017451, effective November 12, 2015.

Fresenius Kabi USA, LLC, submitted two citizen petitions dated March 2, 2018 (Docket No. FDA–2018–P–0964), and March 5, 2018 (Docket No. FDA–2018–P–0967), under 21 CFR 10.30, requesting that the Agency determine whether PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) were withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petitions and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) were not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that these drug products were withdrawn for reasons of safety or effectiveness.

We have carefully reviewed our files for records concerning the withdrawal of PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium

chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that these drug products were not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list PLASMA–LYTE M AND DEXTROSE 5% (calcium chloride, 37 mg/100 mL; dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 119 mg/100 mL; sodium acetate, 161 mg/100 mL; sodium chloride, 94 mg/100 mL; sodium lactate, 138 mg/100 mL) and PLASMA LYTE 148 AND DEXTROSE 5% (dextrose, 5 g/100 mL; magnesium chloride, 30 mg/100 mL; potassium chloride, 37 mg/100 mL; sodium acetate, 368 mg/100 mL; sodium chloride, 526 mg/100 mL; sodium gluconate, 502 mg/100 mL) 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 these drug products 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 these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18311 Filed 8–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–N–0101]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prescription Drug User Fee Cover Sheet; Form FDA 3397

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the Prescription Drug User Fee Cover Sheet, Form FDA 3397, that must be submitted along with certain drug and biological product applications.

DATES: Submit either electronic or written comments on the collection of information by October 23, 2018.

ADDRESSES: 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 October 23, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 23, 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 solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a

written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2005-N-0101 for “Prescription Drug User Fee Cover Sheet; Form FDA 3397.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80

FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comment on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Prescription Drug User Fee Cover Sheet; Form FDA 3397

OMB Control Number 0910-0297—*Extension*

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new human drug applications (NDAs) and BLAs submitted to the Agency for review. Because the submission of prescription drug user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA’s Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs and BLAs.

Respondents to this collection of information are drug and biologics manufacturers that submit NDAs and BLAs. Based on FDA’s database system for fiscal year (FY) 2017, there are an estimated 155 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105-115), as amended by the Food and Drug Administration Reauthorization Act of 2017 (Pub. L. 115-52.)

The total number of annual responses is based on the number of application submissions received by FDA in FY 2017. CDER received 250 annual responses that included the following submissions: 218 NDAs and 32 BLAs. CBER received 12 BLAs. The estimated hours per response are based on past FDA experience with the various submissions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3397	155	1.6903	262	0.5 (30 minutes)	131

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

Our estimated burden for the information collection reflects an overall decrease of 1,724 hours and a corresponding decrease of 3,448 responses. We attribute this program change to the restructuring of the Prescription Drug Use Fee Program fees. The FD&C Act, as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products and discontinued the supplement fee. This resulted in the removal of supplements from the Prescription Drug User Fee Cover Sheet, therefore reducing the burden for this collection of information.

Dated: August 20, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18307 Filed 8–23–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3092]

Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development.” This draft guidance provides recommendations to industry regarding the use of placebos and blinding in randomized controlled clinical trials in development programs for drug or biological products for the treatment of hematologic malignancies and oncologic

diseases regulated by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit either electronic or written comments on the draft guidance by October 23, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and

identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2018–D–3092 for Hematologic Malignancy and Oncologic Disease: Considerations for Use of Placebos and Blinding in Randomized Controlled Clinical Trials for Drug Product Development. Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the