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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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.

FOR FURTHER INFORMATION CONTACT: Lysette Deshields, Center for Drug Evaluation and Research Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993 301–796–3100.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' In the **Federal Register** of November 24, 2014 (79 FR 69857), FDA announced the availability of a revised draft guidance for industry entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' On November 27, 2013, President Obama signed the DQSA into law (Pub. L. 113–54). The DQSA added a new section 503B to the FD&C Act (21 U.S.C. 353b). Under section 503B(b), a compounder can register as an outsourcing facility with FDA. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from certain sections of the FD&C Act, including section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications or abbreviated new drug applications). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

Under section 503B, an outsourcing facility must, at the time of initial registration and twice each year, in June and December, submit to FDA a report identifying the drugs compounded by the facility during the previous 6-month period. For each identified drug, the outsourcing facility must report the following information to FDA for each product that it compounds:

- The active ingredient and strength of active ingredient per unit;
- the source of the active ingredient (bulk or finished drug);
- the National Drug Code (NDC) number of the source drug or bulk active ingredient, if available;
- the dosage form and route of administration;
- the package description;
- the number of individual units produced; and
- the NDC number of the final product, if assigned.[1]

This final guidance explains that registered outsourcing facilities must provide reports to FDA on compounded drugs in SPL format using FDA's electronic submissions system unless FDA grants a request for a waiver of such requirement because use of electronic means is not reasonable for the person requesting the waiver. It supersedes the revised draft guidance entitled ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.''

The comment period for the revised draft guidance ended on January 23, 2015. FDA received three comments on the draft. In response to received comments or on its own initiative, FDA made the following changes and updates in the final guidance: (1) Clarified FDA's definition of the source of the active ingredient used to compound the final product and the information the outsourcing facility should submit to FDA, including the appropriate format of the NDC code; (2) clarified what information submitted as part of a product report will be made public; and (3) made grammatical and other minor editorial changes for clarity. In some cases, comments raised issues that were not directly pertinent to the topics addressed in the revised draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

[1] Section 503B(b)(2)(A)(ii) of the FD&C Act.

II. Paperwork Reduction Act of 1995

This guidance contains 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 have been approved under OMB control number 0910–0827.

III. Electronic Access

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

Dated: December 28, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31789 Filed 12–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–4308]

Labeling of Red Blood Cell Units With Historical Antigen Typing Results; 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 document entitled ''Labeling of Red

Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.'' The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling Red Blood Cell (RBC) units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The draft guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under the biologics regulations. The guidance does not apply to test results for ABO and Rh(D) antigens.

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 April 3, 2017. Submit electronic or written comments on the information collection issues under the Paperwork Reduction Act of 1995 by March 6, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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. [Insert docket number xxxxx] for ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit comments on information collection issues to the Office of Management and Budget in the following ways:

- Fax to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or email to *oira_ubmission@omb.eop.gov.* All comments should be identified with the title, Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.

Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. 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 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry.'' The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with historical antigen typing results. The guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. This guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the

manufacturing and labeling changes under 21 CFR 601.12. The guidance does not apply to test results for ABO and Rh(D) antigens. For ABO and Rh(D) antigens, establishments must follow FDA requirements in 21 CFR 640.5(b), 640.5(c), and 606.121(c)(9) and (13), as well as all other applicable requirements.

At the AABB–FDA Liaison Meeting held on April 12, 2012, AABB stated that it is the practice of some blood collection establishments to provide historical RBC antigen typing results to transfusion services using a tie-tag attached to the RBC unit. AABB asked for recommendations from FDA regarding labeling of RBC units with historical RBC antigen typing results. FDA's Blood Products Advisory Committee discussed this topic on December 4, 2012, and supported the concept of using historical RBC antigen typing results to label RBC units.

AABB has revised its standards to include accommodations for labeling RBC units with historical RBC typing results. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

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 the current thinking of FDA on labeling of red blood cell units with historical antigen typing results. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

The draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal Agencies must obtain approval from 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 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 comments 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.

Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Draft Guidance for Industry; OMB Control No. 0910–NEW

The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The draft guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood collection establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under 21 CFR 601.12.

Description of Respondents: Establishments that collect blood and blood components for transfusion, transfusion services, and licensed blood collection establishments.

Burden Estimate: We believe that the information collection provisions in the draft guidance do not create a new burden for respondents and are part of usual and customary business practices. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

We believe that facilities have already developed standard operating procedures for putting the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR 606.100, 606.121, 606.160, 606.171 have been approved under OMB control number 0910–116, 0910–0795 and 0910–0458.

III. 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: December 27, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31771 Filed 12–30–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development, Manufacture and Commercialization of Gene Therapy Products for Human Gene Therapy Use To Treat and/or Prevent Methylmalonic Acidemia (MMA)

AGENCY: National Institutes of Health (NIH).

ACTION: Notice.

SUMMARY: The National Human Genome Research Institute (NHGRI), an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive commercialization patent license to practice the inventions embodied in the Patent Applications listed in the Supplementary Information section of this notice License to Selecta Biosciences (''Selecta'') located in Watertown, Massachusetts.