

tissue establishments for determining HCT/P donor eligibility. These requirements include the need to screen and test potential donors of HCT/Ps for relevant communicable disease agents and diseases (RCDADs).

The regulations under part 1271, subpart C, list the following RCDADs for all cells and tissues: Human immunodeficiency virus, types 1 and 2; hepatitis B virus; hepatitis C virus; human transmissible spongiform encephalopathy; and *Treponema pallidum*. These regulations also list human T-lymphotropic virus type I and type II as RCDADs for viable, leukocyte-rich cells and tissues. For reproductive cells or tissues, a disease agent or disease of the genitourinary tract includes *Chlamydia trachomatis* and *Neisseria gonorrhoea*. In addition, the regulations under part 1271, subpart C, recognize that over time as new infectious diseases emerge there would be the need to designate additional RCDADs. The regulations describe the criteria for identifying new RCDADs. These criteria include that the disease or disease agent is potentially transmissible by a HCT/P: Either it has sufficient incidence and/or prevalence to affect the donor population; or if it were released in a manner to place potential donors at risk that it could be fatal or life-threatening, and that there were appropriate screening and legally marketed screening tests available for it. However, the regulations under part 1271, subpart C, do not specify the deliberative and scientific processes necessary to apply the criteria.

This workshop will describe currently available scientific methods to characterize both epidemiologic and biological features of emerging diseases and disease agents, and discuss their potential use in evaluating HCT/P infectious diseases risks for the purpose of identifying new RCDADs for the purposes of the HCT/P regulatory framework. Assessing the overall risk of a particular disease agent or disease to recipients of HCT/Ps requires consideration of multiple factors, including the presence of the disease agent or disease in the HCT/P donor population, potential for transmission by an HCT/P, and the potential morbidity or mortality in the recipient. In many cases, information for one or more of these factors may be limited or incomplete.

II. Topics for Discussion at the Public Workshop

The workshop is intended as a scientific discussion regarding the current methods available to identify and characterize infectious disease risks

related to HCT/Ps. Topics discussed will include: (1) Estimating disease incidence and/or prevalence in the potential HCT/P donor population, (2) assessing the potential transmissibility of a disease by HCT/Ps, and (3) understanding the capabilities of current screening and testing methodologies. The workshop will also include discussion on how available information can be used to characterize the overall infectious disease risks posed by HCT/Ps.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site at <https://www.eventbrite.com/e/identification-and-characterization-of-hctp-infectious-disease-risks-public-workshop-registration-24465329459>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register by February 6, 2017. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. Attendance for this workshop is in-person only. FDA will post the agenda approximately 5 days before the workshop at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm490175.htm>.

If you need special accommodations because of disability, please contact Monica Kapoor or Stacey Rivette no later than 7 days in advance of the meeting by email at CBERPublicEvents@fda.hhs.gov with the subject line titled "HCT/P Workshop."

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the Internet at <http://www.fda.gov/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/ucm525001.html>.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-0269]

Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry entitled "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act." This guidance sets forth FDA's policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

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

ADDRESSES: You may submit comments 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):* 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. FDA-2016-D-0269 for “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” 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 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 <https://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 <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 the 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: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5197, Silver Spring, MD, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for industry entitled “Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act.” Section 503A 21 U.S.C. 353a), added to the FD&C Act by the Food and Drug Administration Modernization Act in 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements);
- 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 drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

A compounded drug product may be eligible for the exemptions under

section 503A of the FD&C Act only if it is, among other things, compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient. Among other conditions, to qualify for the exemptions under section 503A, the drug product must be compounded by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a) of the FD&C Act).

This guidance sets forth FDA’s policy concerning certain prescription requirements for compounding human drug products for identified individual patients under section 503A of the FD&C Act. It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use.

In the **Federal Register** of April 18, 2016 (81 FR 22617), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on July 18, 2016. FDA received 111 comments on the draft guidance. In response to received comments, FDA made certain changes to the guidance to clarify particular points. FDA also removed provisions concerning notations on prescriptions and recordkeeping. The Agency intends to address these matters in future policy documents.

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 the prescription requirement under section 503A of the FD&C 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.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/Guidance/ComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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