FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Christina Vert at *ctgtac@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08022 Filed 4–13–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0108]

Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' This guidance is intended to assist abbreviated new drug application (ANDA) applicants that reference a drug product intended for parenteral, ophthalmic, or otic use in seeking approval of a drug that is qualitatively (Q1) different or quantitatively (Q2) different from the reference listed drug (RLD) with respect to the pH adjuster(s). This draft guidance describes how FDA intends to evaluate a request for a waiver of Agency requirements for a Q1 or Q2 difference in pH adjuster, including recommendations on the type of information to provide in support of such a waiver request. This draft guidance also includes recommendations on the timing and process for submitting such waiver requests.

DATES: Submit either electronic or written comments on the draft guidance by June 13, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.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–2022–D–0108 for ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' 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, 240–402–7500.

- 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.govinfo.gov/content/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, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Melissa Mannion, Center for Drug

Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1611, Silver Spring, MD 20993–0002, 301–796–2747.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' This 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 ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' 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.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) does not require an ANDA to have the same inactive ingredients as the RLD.[1] Section 505(j)(4)(H) of the FD&C Act (21 U.S.C. 355(j)(4)(H)) does, however, state that an ANDA shall not be approved if information submitted in the application (or other information available) shows (1) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (2) the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included is unsafe under such conditions.[2]

The Agency has interpreted section 505(j)(4)(H) of the FD&C Act as permitting the Agency to deny approval of an ANDA ''if there is a reasonable basis to conclude that its inactive ingredients or composition raise serious questions about the drug's safety.'' [3]

The regulations at § 314.94(a)(9)(iii) and (iv) (21 CFR 314.94(a)(9)(iii) and (iv)), with parallel provisions in the approval regulations at § 314.127(a)(8)(ii)(B) and (C) (21 CFR 314.127(a)(8)(ii)(B) and (C)), specify that FDA will consider an inactive ingredient in, or the composition of, a generic drug product intended for parenteral, ophthalmic, or otic use to be unsafe and will refuse to approve the ANDA unless the generic drug product contains the same inactive ingredients (with certain listed exceptions) in the same concentration as the RLD. These regulations also identify permissible differences in certain inactive ingredients for drug products intended for parenteral, ophthalmic, or otic use, commonly referred to as ''exception excipients,'' if the ANDA contains sufficient information to demonstrate that any such differences do not affect the safety or efficacy of the drug. The regulations do not, however, expressly identify pH adjusters as one of these ''exception excipients,'' and, as such, the inactive ingredient requirements in § 314.94(a)(9)(iii) and (iv) apply to pH adjusters.

Under § 314.99(b) (21 CFR 314.99(b)), however, an applicant may ask FDA to waive any requirement that applies to the applicant under §§ 314.92 through 314.99 (21 CFR 314.92 through 314.99). Such a request under § 314.99(b) must comply with the requirements at 21 CFR 314.90. FDA may grant a § 314.99(b) waiver if the Agency finds one of the following: (1) The applicant's compliance with the requirement is unnecessary for the Agency to evaluate the ANDA or compliance cannot be achieved; (2) the applicant's alternative submission satisfies the requirement; or (3) the applicant's submission otherwise justifies a waiver. Even if FDA grants a waiver of a requirement in §§ 314.92 through 314.99 in a particular application, the application still must meet all applicable statutory requirements for approval. If FDA grants the applicant's waiver request with respect to a requirement under §§ 314.92 through 314.99, the waived requirement will not constitute a basis for refusal to approve an ANDA under § 314.127. Thus, an ANDA applicant for a drug product intended for parenteral, ophthalmic, or otic use who seeks to use a pH adjuster(s) that is Q1 or Q2 different from the RLD may ask the Agency to waive the inactive ingredient requirements at § 314.94(a)(9)(iii) or (iv) for the pH adjuster(s). This draft guidance document provides recommendations on (1) the type of information that applicants should consider submitting with a § 314.99(b) waiver request when an ANDA applicant asks the Agency to waive the inactive ingredient requirements for pH adjusters and (2) the format and process for submitting such waiver requests.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 320 been approved under OMB control numbers 0910–0014 and 0910–0291; and the collections of information for the submission of controlled correspondence related to generic drug development and FDA approval have been approved under OMB control number 0910–0797.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08012 Filed 4–13–22; 8:45 am]

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[1] See section 505(j)(2)(A) of the FD&C Act (setting forth the required contents of an ANDA).

[2] Section 505(j)(4)(H) of the FD&C Act.

[3] 21 CFR 314.127(a)(8)(ii); 54 FR 28871 at 28903 (July 10, 1989).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0313]

Lisett Raventos: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Lisett Raventos from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Lisett Raventos was convicted of a felony under Federal law for conduct that relates to the development or approval, including the process of development or approval, of a drug product under the FD&C Act. Ms. Raventos was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be