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FDA is announcing the availability of a draft guidance for industry entitled ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for Parenteral, Ophthalmic, or Otic Use.'' This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Considerations for Waiver Requests for pH Adjusters in Generic Drug Products Intended for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

debarred. As of December 29, 2021 (30 days after receipt of the notice), Ms. Raventos had not responded. Ms. Raventos's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable April 14, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On March 5, 2021, Ms. Raventos was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against her in the U.S. District Court for the Southern District of Florida, after her plea of guilty to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: Ms. Raventos was a clinical study coordinator at Unlimited Medical Research, LLC. From about September 2013 through June 2016, Ms. Raventos conspired with others to unlawfully enrich herself by making materially false representations about clinical trials; fabricating data and the participation of subjects in those clinical trials; concealing from FDA, sponsors, and contract research organizations the fact that the data and participation of subjects had been fabricated; and inducing sponsors and contract research organizations to pay money for Ms. Raventos and her co-conspirators' own benefit. Specifically, one of Ms. Raventos's co-conspirators entered into a contract with a Contract Research Organization (CRO), retained by a drug manufacturer (Sponsor) to hire clinical investigators and to manage clinical trials. Ms. Raventos's co-conspirator entered into a contract with the CRO to conduct a clinical trial at Unlimited Medical Research site in return for payment. The clinical trial was for an investigational drug intended to treat pediatric asthma in children between the ages of 4 and 11 years.

Ms. Raventos represented herself to be the Site Director, Director of Clinical Operations, and the Study Coordinator for this clinical trial. In those roles, Ms. Raventos was responsible for complying with the study protocol, including administering the study drug to subjects in the study and preparing written records, known as case histories, which documented the participation of subjects in the clinical trial. Ms. Raventos participated in a scheme to defraud the Sponsor by fabricating the data and participation of subjects in the clinical trial in a variety of ways: Ms. Raventos and her co-conspirators falsified medical records to portray persons as legitimate study subjects when they were not. In addition, Ms. Raventos and her co-conspirators made it appear as though pediatric subjects made scheduled visits to Unlimited Medical Research when they had not, made it appear as though subjects had taken the study's drugs as required when they had not, and made it appear that the study subjects had received checks as payment when they had not.

As a result of this conviction, FDA sent Ms. Raventos by certified mail on November 19, 2021, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Ms. Raventos was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Ms. Raventos an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Raventos received the proposal on November 29, 2021. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any contentions concerning her debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Raventos has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Raventos is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see section 306(a)(2)(A) and (c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Raventos, in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Raventos provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Raventos during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a ''drug product'' is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd)).

Any application by Ms. Raventos for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA–2021–N–0313 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: April 11, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08025 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–N–0008]

Patient Engagement Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the CDRH Patient Engagement Advisory Committee. The general function of the committee is to provide advice to the Commissioner of Food and Drugs, or designee, on complex scientific issues relating to medical devices, the regulation of devices, and their use by patients. The meeting will be open to the public.

DATES: The meeting will take place virtually on July 12, 2022, from 10 a.m. to 4 p.m. Eastern Time and on July 13, 2022, from 10 a.m. to 2 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* Information on how to access the webcast will be made available no later than 2 business days prior to the meeting at *https://www.fdalive.com/peac.*

FOR FURTHER INFORMATION CONTACT: Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993–0002, *letise.williams@fda.hhs.gov,* 301–796–8398, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link or call the advisory committee information line to learn about possible modifications before the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On July 12 and 13, 2022, the committee will discuss and make recommendations on the topic of ''Augmented Reality (AR) and Virtual Reality (VR) Medical Devices.'' AR/VR devices are increasingly applied to healthcare settings across the patients' care continuum. From diagnostics to clinical decision making, to surgical support, and to directly treating patients, AR/VR devices are used across multiple medical specialties. These devices have novel attributes and considerations for the end users that impact FDA's evaluation of the device's safety and effectiveness. The novel attributes of digital health visualization, tracking techniques, embedded software among other factors present unique challenges for pre- and postmarked evaluation. The recommendations provided by the committee will address factors FDA and industry should consider when evaluating the benefits, risks, and the extent of uncertainty in the benefit-risk information for AR/VR medical devices. The committee will also consider specific challenges related to specific populations (*e.g.,* pediatric or cognitively impaired) who may use this technology. Additionally, the committee will discuss ways patient perspectives could be incorporated in FDA and industry benefit-risk decision making, as well as the healthcare provider decision-making process related to using or prescribing the technology.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background materials will be available at *https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee.* Select the link for the 2022 Meeting Materials. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Oral presentations from the public will be scheduled on July 12, 2022, between approximately 2:30 p.m. Eastern Time to 3:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**). The notification should include a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 10, 2022. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 14, 2022. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the committee may send written submissions to the contact person on or before June 20, 2022.

Virtual Breakout Session: Individuals interested in participating in the virtual breakout scenario discussions will need to sign up to participate on or before June 28, 2022. The signup sheet, as well as additional information pertaining to the virtual scenario discussions, will be available at *https://www.fdalive.com/peac.* Everyone who signs up in advance and provides a valid email address will receive an email at least 2 days prior to the meeting with information on how to access the virtual platform that will host the virtual breakout scenario discussions. Please note that due to limited technology capacity, participation in the virtual breakout scenario discussions will be limited to 150 participants. Once capacity reaches 150 participants, the breakout session will be closed to additional participants. Additional information regarding the virtual breakout scenario discussions will be provided at *https://www.fdalive.com/peac.*

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to