allow CMS to obtain more information about who is submitting requests for ODR and whether the service or claim is being provided by a contract or non-contract provider. The timeliness requirement for ODR will also be eliminated to be consistent with Part D reporting. In addition, the number of data reporting elements of grievances is reduced from 23 to 19. The reporting sections for Private Fee For Service (PFFS) Payment Dispute Resolution Process and Mid-Year Network Changes will also be suspended. *Form Number:* CMS–10261 (OMB control number: 0938–1054); *Frequency:* Yearly and semi-annually; *Affected Public:* Private sector (business or other for-profits); *Number of Respondents:* 432; *Total Annual Responses:* 3,024; *Total Annual Hours:* 127,329. (For policy questions regarding this collection contact Maria Sotirelis at 410–786–0552.)

6. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Consumer Assessment of Healthcare Providers and Systems Outpatient and Ambulatory Surgery (OAS CAHPS) Survey; *Use:* The information collected in the national implementation of Outpatient/Ambulatory Surgery Patient Experience of Care Survey (A/ASPECS) will be used to: (1) Provide a source of information from which selected measures can be publicly reported to beneficiaries to help them make informed decisions for outpatient surgery facility selection; (2) aid facilities with their internal quality improvement efforts and external benchmarking with other facilities; and (3) provide us with information for monitoring and public reporting purposes. *Form Number:* CMS–10500 (OMB control number: 0938–1240); *Frequency:* Once; *Affected Public:* Individuals and households; *Number of Respondents:* 633,304; *Total Annual Responses:* 633,304; *Total Annual Hours:* 153,592. (For policy questions regarding this collection contact Memuna Ifedirah at 410–786–6849).

7. *Type of Information Collection Request:* New collection (Request for new OMB control number); *Title of Information Collection:* Medicare Enrollment Application for Physician and Non-Physician Practitioners; *Use:* The application is used by Medicare contractors to collect data to ensure that the applicant has the necessary credentials to provide the health care services for which they intend to bill Medicare, including information that allows the Medicare contractor to correctly price, process and pay the applicant's claims. This application collects information to ensure that only legitimate physicians, non-physician practitioners, and other eligible professionals are enrolled in the Medicare program. It is meant to be the first line defense to protect our beneficiaries from illegitimate providers and to protect the Medicare Trust Fund against fraud. It also gathers information that allows Medicare contractors to ensure that the provider/supplier is not sanctioned from the Medicare and/or Medicaid program(s), or debarred, suspended or excluded from any other Federal agency or program. *Form Number:* CMS–855i (OMB control number: 0938–NEW); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector (not-for-profit institutions); *Number of Respondents:* 513,872; *Total Annual Responses:* 1,370,078; *Total Annual Hours:* 1,000,167. For policy questions regarding this collection contact Kimberly McPhillips at (410)-786–5374.

Dated: July 10, 2018.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2018–15038 Filed 7–12–18; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1156]

Q3D(R1) Elemental Impurities; International Council for Harmonisation; 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 ''Q3D(R1) Elemental Impurities.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation (ICH), formerly the International Conference on Harmonisation. The draft guidance revises the existing ICH guidance for industry ''Q3D Elemental Impurities'' and provides an updated permitted daily exposure (PDE) for the cadmium inhalation route of exposure. The updated PDE of 3 micrograms (µg)/day is based on a modifying factor approach like that used for calculating the PDEs for the cadmium oral and parenteral routes of exposure. The draft guidance is intended to correct a calculation error in the PDE for cadmium by the inhalation route of exposure. Following deliberations within the Q3D Expert Working Group, the revised calculation is based on a modifying factor approach that is consistent with the oral and parenteral PDE calculations.

DATES: Submit either electronic or written comments on the draft guidance by August 13, 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–2013–D–1156 for ''Q3D(R1) Elemental Impurities.'' 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 office 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.

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

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, or 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 that office in processing your requests. The 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 guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Tim McGovern, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6300, Silver Spring, MD 20993–0002, 240–402–0477.

Regarding the ICH: Amanda Roache, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1176, Silver Spring, MD 20993–0002, 301–796–4548.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, regulatory authorities and industry associations from around the world have participated in many important initiatives to promote international harmonization of regulatory requirements under the ICH. FDA has participated in several ICH meetings designed to enhance harmonization and FDA is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and reduce differences in technical requirements for drug development among regulatory agencies.

ICH was established to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products for human use among regulators around the world. The six founding members of the ICH are the European Commission; the European Federation of Pharmaceutical Industries Associations; FDA; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; and the Pharmaceutical Research and Manufacturers of America. The Standing Members of the ICH Association include Health Canada and Swissmedic. Any party eligible as a Member in accordance with the ICH Articles of Association can apply for membership in writing to the ICH Secretariat. The ICH Secretariat, which coordinates the preparation of documentation, operates as an international nonprofit organization and is funded by the Members of the ICH Association.

The ICH Assembly is the overarching body of the Association and includes representatives from each of the ICH members and observers. The Assembly is responsible for the endorsement of draft guidelines and adoption of final guidelines. FDA publishes ICH guidelines as FDA guidance.

In May 2018, the ICH Assembly endorsed the draft guideline entitled ''Q3D(R1) Elemental Impurities'' and agreed that the guideline should be made available for public comment. The draft guideline is the product of the Quality Expert Working Group of the ICH. Comments about this draft will be considered by FDA and the Quality Expert Working Group.

The draft guidance revises the existing guidance for industry ''Q3D Elemental Impurities'' and provides an updated permitted daily exposure (PDE) for the cadmium inhalation route of exposure. The revision was initiated following identification of a calculation error in the original text. The updated PDE of 3 μg/day is based on a modifying factor approach that is consistent with the method used for calculating the PDEs for the oral and parenteral routes of exposure.

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 ''Q3D(R1) Elemental Impurities.'' 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

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

Dated: July 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14971 Filed 7–12–18; 8:45 am]

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