| Grantee respondent type | Form/report name | Number of respondents | Number of responses per respondent | Average burden per response (in minutes) | Total burden hours |
|---|---|---|---|---|---|
| SMP | Individual Interaction | 6,935 | 41 | 5 | 23,694.58 |
| SMP | Team Member | 216 | 31 | 5 | 558 |
| SMP | SIRS Team Member Activity | 216 | 31 | 5 | 558 |
| *SMP | OIG Report | *0 | 0 | 0 | 0 |
| *SMP | Time Spent Report | *0 | 0 | 0 | 0 |
| SHIP/MIPPA | Media Outreach & Education | 3,750 | 15 | 4 | 3,750 |
| SHIP/MIPPA | Group Outreach & Education | 3,750 | 15 | 4 | 3,750 |
| SHIP/MIPPA | STARS Team Member | 216 | 75 | 5 | 1,350 |
| SHIP/MIPPA | Beneficiary Contact | 15,000 | 233 | 5 | 291,250 |
| *SHIP/MIPPA | SHIP Performance Report | *0 | 0 | 0 | 0 |
| *SHIP/MIPPA | Resource Report | *0 | 0 | 0 | 0 |
| *SHIP/MIPPA | MIPPA Performance Report | *0 | 0 | 0 | 0 |
| SHIP/MIPPA | SHIP Team Member Activity | 216 | 40 | 7 | 1,008 |
| SHIP/MIPPA | Team Member Training | 216 | 40 | 6 | 864 |
| *SHIP/SMP/MIPPA | Summary Reports | *0 | 0 | 0 | 0 |
| *SHIP/MIPPA | Part D Enrollment Outcomes Report | *0 | 0 | 0 | 0 |
| Totals | | 37,666 | 571 | | 329,294.31 |

*This data collection activity is an automated task in the system and does not compute to an estimate of time for burden.

Dated: December 21, 2023.

**Alison Barkoff,**

*Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.*

[FR Doc. 2023–28623 Filed 12–27–23; 8:45 am]

**BILLING CODE 4154–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–D–5408]**

### Reformulating Drug Products That Contain Carbomers Manufactured With Benzene; 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 final guidance for industry entitled ''Reformulating Drug Products That Contain Carbomers Manufactured With Benzene.'' The purpose of this guidance is to provide recommendations to applicants and manufacturers on what tests should be performed and what documentation should be submitted or available to support the reformulation of drug products that use carbomers manufactured with benzene. Certain United States Pharmacopeia (USP) carbomer monographs currently allow for unacceptable levels of benzene, which raises safety concerns. FDA has requested that the USP omit (or remove) these monographs, and applicants and manufacturers may need to reformulate their drug products to avoid use of these carbomers. This guidance provides recommendations for tests and documentation related to reformulation based on various routes of administration and dosage forms of affected drug products, and provides recommendations for application holders on the appropriate submission types to notify the Agency of reformulation changes. The intended effect of this guidance is to, as appropriate, provide a less burdensome risk-based approach to reformulation submissions relative to existing guidances on scale-up and post-approval changes (SUPAC), and address the immediate public health need to expedite the discontinuation of the use of carbomers manufactured with high levels of benzene in drug products.

**DATES:** The announcement of the guidance is published in the **Federal Register** on December 28, 2023.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances 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–2023–D–5408 for ''Reformulating Drug Products That Contain Carbomers Manufactured With Benzene; Guidance for Industry.'' 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 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:** Pallavi Nithyanandan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4156, Silver Spring, MD 20993–0002, 301–796–7546, *Pallavi.Nithyanandan@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a guidance for industry entitled ''Reformulating Drug Products That Contain Carbomers Manufactured With Benzene.'' FDA is issuing this guidance consistent with its good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). The Agency is implementing this guidance without prior public comment because it has determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2) and (3)). FDA made this determination because benzene is a known human carcinogen, and the Agency seeks to facilitate the transition away from using carbomers manufactured with high levels of benzene. Publishing this guidance without prior public comment addresses the immediate public health need to expedite the discontinuation of the use of these carbomers and provides a less burdensome risk-based approach to applicant submissions, relative to existing guidances on SUPAC. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

The purpose of this guidance is to provide recommendations to applicants and manufacturers on what tests should be performed and what documentation should be submitted or available to support the reformulation of drug products that use carbomers manufactured with benzene. Certain USP carbomer monographs currently allow for unacceptable levels of benzene, which raises safety concerns. FDA has requested that the USP omit (or remove) these monographs, and applicants and manufacturers may need to reformulate their drug products to avoid use of these carbomers.

Carbomers are a group of polymers composed of acrylic acid. They are widely used as inactive ingredients in drug products as fillers, emulsifiers, gelling agents, and binding agents. There are carbomers currently used as inactive ingredients that are manufactured using benzene as a polymerization solvent. Benzene is a known human carcinogen. As such, both the International Conference for Harmonisation (ICH) guidance for industry entitled ''Q3C—Tables and List'' (available at *https://www.fda.gov/media/133650/download*) and USP General Chapter <467> ''Residual Solvents'' designate benzene as a Class 1 solvent (*i.e.,* solvents that should be avoided) and recommend that benzene should not be employed in the manufacture of drug substances, excipients, and drug products. However, there are still several grades of carbomers that are manufactured using benzene as a solvent being used in pharmaceutical products even though alternative grades of carbomers are available that are manufactured without the use of benzene.

At the time of publication, carbomers manufactured with benzene may fall under the United States Pharmacopeia-National Formulary (USP–NF) monographs Carbomer 934, Carbomer 934P, Carbomer 940, Carbomer 941, or Carbomer 1342. These monographs permit benzene levels as high as 5,000 parts per million (ppm), which is significantly higher than the limit of 2 ppm on benzene as an impurity in the USP–NF Carbomer Homopolymer, Carbomer Copolymer, and Carbomer Interpolymer monographs. To avoid confusion, and because of the safety concerns associated with these unacceptable levels of benzene permitted by these monographs, FDA has asked the USP to remove (or ''omit'') the Carbomer 934P, Carbomer 940, Carbomer 934, Carbomer 1342, and Carbomer 941 monographs from the USP–NF compendium.

The guidance represents the current thinking of FDA on ''Reformulating Drug Products That Contain Carbomers Manufactured With Benzene.'' 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

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 pertaining to the submission of new drug applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice requirements have been approved under OMB control number 0910–0139.

## III. Electronic Access

Persons with access to the internet may obtain the 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: December 21, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–28675 Filed 12–27–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–N–0039]**

### Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) Center for Biologics Evaluation and Research (CBER) is announcing the availability of version 2.3 of the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports (ICSRS) for Vaccines (Specifications). The version update is not applicable to CBER-regulated drug products marketed for human use with approved New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs); CBER-regulated therapeutic biological products marketed for human use with approved Biologic License Applications (BLAs); Whole Blood or blood components; and human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated solely under the Public Health Service Act.

**ADDRESSES:** You may submit either electronic or written comments 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–2021–N–0039 for ''Electronic Submissions; Update to the Specifications for Preparing and Submitting Postmarket Individual Case Safety Reports for Vaccines; Technical Specification''. 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 laws. 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.

**FOR FURTHER INFORMATION CONTACT:** Victoria Wagman, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

### Background

CBER is announcing the availability of version 2.3 of the Specifications for Preparing and Submitting Postmarket ICSRs for Vaccines (available at *https://www.fda.gov/industry/about-esg/cber-vaccine-icsr-implementation*). The version update has been prepared to provide updated specifications on submitting re-challenge information, to correct values for the 'Vaccination Facility Type' (FDA.G.k.4.r.14.8), and to record modifications to the 'Attachment File Name' (FDA.C.1.6.1.r.3) as well as various document formatting refinements. In addition, version 2.3 includes updated business rules (Appendix I of the Specifications) which provide details on data field specifications. The version update is not applicable to CBER-regulated drug products marketed for human use with approved NDAs and ANDAs; CBER-regulated therapeutic biological products marketed for human use with approved BLAs; Whole Blood or blood components; and HCT/Ps regulated solely under section 361 of the Public Health Service Act (42 U.S.C. 264).

At this time, all existing eVAERS submitters (vaccine manufacturers and others responsible for reporting ICSRs for vaccines) have successfully transitioned to reporting in version 2.2.