The estimated annual third-party disclosure burden for labeling is based on data available to the Agency, our knowledge of and experience with cosmetics, and informal communications with industry. The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: a declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments needed to design labels because they increase the number of label elements that establishments must consider when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices. Regarding the new statutory labeling requirements for products intended for professional use only and contact information for manufacturers to receive reports of adverse events, we estimate that there will be a capital cost of $94,080,000 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time cost. We estimate that the total third-party disclosure burden is 178,806 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

| MoCRA citation; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Sec. 607(a)(1) of the FD&C Act; initial registrations .... | 3,400 | 1 | 3,400 | 1 ..... | 3,400 |
| Sec. 607(a)(2) and (5) of the FD&C Act; biennial registration renewals. | 1,700 | 1 | 1,700 | 0.25 (15 minutes) | 425 |
| Sec. 607(a)(4) of the FD&C Act; registration updates .. | 100 | 1 | 100 | 0.25 (15 minutes) | 25 |
| Sec. 607(f) of the FD&C Act; post-hearing corrective action plan. | 5 | 1 | 5 | 10 ..... | 50 |
| Sec. 607(c)(1) and (2) of the FD&C Act; cosmetic product listing. | 3,400 | 5 | 17,000 | 0.50 (30 minutes) | 8,500 |
| Sec. 607(c)(3) of the FD&C Act; product listing renewals. | 3,400 | 5 | 17,000 | 0.25 (15 minutes) | 4,250 |
| Sec. 607(c)(5) of the FD&C Act; product listing updates. | 200 | 1 | 200 | 0.25 (15 minutes) | 50 |
| Total ..... | ..... | ..... | ..... | ..... | 16,700 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of reporting burden hours on information from the VCRP, because it provided the best available data to FDA in terms of the number of respondents and responses. We believe that the VCRP reflected less than half of cosmetic manufacturers and processors because it was a voluntary system. Accordingly, we doubled our estimate for the number of respondents registering and used this number to estimate other activities related to facility registration and cosmetic product listing. Based on a review of the information collection since our last request for OMB approval, we have increased our estimate to account for an anticipated increase in respondents resulting from new statutory requirements.

Dated: April 26, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–09178 Filed 4–28–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–1052]**

### Food and Drug Administration Data and Technology Strategic Plan; Request for Information and Comments; Extension of Comment Period

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

**ACTION:** Notice; request for information and comments; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing a request for information and comments that appeared in the **Federal Register** of April 13, 2023. In that notice, FDA requested information and comments on the FDA Data and Technology Strategic Plan. The Agency is taking this action to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the notice published April 13, 2023 (88 FR 22453). Either electronic or written comments must be submitted by June 12, 2023, to ensure that the Agency considers your comment on this request for information and comments before it begins work on the strategic plan.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 12, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*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–N–1052 for ''FDA Data and Technology Strategic Plan.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

**FOR FURTHER INFORMATION CONTACT:** Casi Alexander, Office of Digital Transformation, Food and Drug Administration, FDA Library, 5630 Fishers Lane, Rm. 1087, Rockville, MD 20857, 240–402–5171, *Casi.Alexander@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 13, 2023, FDA published a notice announcing a request for information and comments entitled ''FDA Data and Technology Strategic Plan; Request for Information and Comments.'' Interested persons were originally given until May 15, 2023, to comment on the document. The Agency has elected to extend the comment period so that all interested parties are able to more thoroughly consider the request for input. FDA is extending the comment period for 30 days, until June 12, 2023. The Agency believes that this 30-day extension allows adequate time for interested persons to submit comments.

Dated: April 26, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–09169 Filed 4–28–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–1443]**

### Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Elements and Terminologies; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is requesting comment on the draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Elements and Terminologies for the electronic submission of PQ/CMC data. Building on the Agency's previous **Federal Register** notices published on July 11, 2017, and March 18, 2022, requesting comments on PQ/CMC data elements and controlled terminology, the Agency is continuing to seek comment on the accuracy, suitability, and appropriateness of revised and/or new data elements and terminologies for submission of PQ/CMC data. In addition, the progress toward the establishment of standardized pharmaceutical data elements and terminologies will require further interactions between the Agency and interested parties and various stakeholders, including industry. Accordingly, FDA is planning to request comment on additional PQ/CMC data elements and terminologies over time. FDA is establishing an open docket to facilitate efficient receipt of comments and public posting of updated draft documents on PQ/CMC data elements and terminologies.

**DATES:** Comments may be submitted to this docket 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,