For CMS *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/meetings.*

FOR FURTHER INFORMATION CONTACT: Traci Ramirez, Program Specialist, CDC, 3311 Toledo Road, Hyattsville, Maryland 20782, Telephone (301) 458–4454; *TRamirez@cdc.gov.*

SUPPLEMENTARY INFORMATION: *Purpose:* The ICD–10 Coordination and Maintenance (C&M) Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical Modification and ICD–10 Procedure Coding System.

Matters To Be Considered: The tentative agenda will include discussions on ICD–10–CM and ICD–10–PCS topics listed below. Agenda items are subject to change as priorities dictate.

Please refer to the posted agenda for updates one month prior to the meeting.

ICD–10–PCS Topics

Vertebral Body Tethering
Removal of a Transplanted/Rejected Kidney
Isotope Administration
Administration of Lifileucel
Administration of Narsoplimab
Insertion of Implantable Bone Void Filler
Single-Use Duodenoscope
Administration of Immune Effector Cell Therapy
Spinal Stabilization
Administration of Idecabtagene Vicleucel (ide-cel)
Restriction of Coronary Sinus Embolic Protection

ICD–10–CM Topics:

Complications of immune effector cellular (IEC) therapy
Endometriosis
Immune Effector Cell Associated Neurotoxicity Syndrome (ICANS)
Addenda

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2020–16000 Filed 7–22–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0490]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cosmetic Labeling Regulations and Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 24, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0599. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Cosmetic Labeling Regulations—21 CFR part 701 and Voluntary Cosmetic Registration Program—21 CFR parts 710 and 720

OMB Control Number 0910–0599—Revision

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 331, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

I. Cosmetic Labeling Regulations

FDA's cosmetic labeling regulations are codified in part 701 (21 CFR part 701). Section 701.3 requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 requires the label of a cosmetic product to declare the net quantity of contents of the product. The information collection provisions found in part 701 are currently approved under OMB control number 0910–0027. To improve the efficiency of Agency operations, we are consolidating these information collection elements into OMB control number 0910–0599.

II. Voluntary Cosmetic Registration Program

Information collection associated with our Voluntary Cosmetic Registration Program (VCRP) are found in parts 710 and 720 (21 CFR parts 710 and 720). Participants have the option of submitting information via paper forms or via an online interface. The use of the term ''form'' refers to both the paper form and the online system.

Pursuant to part 710, we request that establishments that manufacture or package cosmetic products voluntarily register with us using Form FDA 2511 entitled ''Registration of Cosmetic Product Establishment.'' The online version of Form FDA 2511 is available on our VCRP website at *https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp.* We encourage online registration of Form FDA 2511 because it is faster and more efficient for the filer and the Agency. A registering facility will receive confirmation of online registration, including a registration number by

email. The online system also allows for amendments to past submissions.

Because registration of cosmetic product establishments is not mandatory, voluntary registration provides FDA with the best information available about the locations, business trade names, and types of activity (manufacturing or packaging) of cosmetic product establishments. We store the registration information in a computer database and use the information to generate mailing lists for distributing regulatory information and for inviting firms to participate in workshops on topics in which they may be interested. Registration is permanent, although we request that respondents submit an amended Form FDA 2511 if any of the originally submitted information changes.

Pursuant to part 720, we request firms that manufacture, pack, or distribute cosmetics to file with the Agency an ingredient statement for each of their products. Filing of cosmetic product ingredient statements is also voluntary. Ingredient statements for new submissions are reported on Form FDA 2512, ''Cosmetic Product Ingredient Statement,'' and on Form FDA 2512a, a continuation form. Amendments to product formulations also are reported on Forms FDA 2512 and FDA 2512a. When a firm discontinues the commercial distribution of a cosmetic, we request that the firm notify FDA that they have discontinued a cosmetic product formulation by submitting an amended Form FDA 2512. If any of the information submitted on these forms is confidential, the firm may submit a request for confidentiality of a cosmetic ingredient.

FDA's use of an electronic submission system has been designed to make it easier for participants to provide information to FDA about their products. The online version of Forms FDA 2512 and FDA 2512a are available on our VCRP website at *https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp.*

Description of Respondents: Respondents to this collection of information include cosmetic manufacturers, packers, and distributors. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of April 3, 2020 (85 FR 18993), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received communicating general support for the information collection.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
701.3; ingredients in order of predominance	1,518	21	31,878	1	31,878
701.11; statement of identity	1,518	24	36,432	1	36,432
701.12; name and place of business	1,518	24	36,432	1	36,432
701.13; net quantity of contents	1,518	24	36,432	1	36,432
Total					141,174

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

The estimated annual third-party disclosure burden is based on data available to the Agency, our knowledge of and experience with cosmetics, and 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. We estimate that the total third-party disclosure burden is 141,174 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section or part	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (minutes)	Total hours
Part 710 (registrations)	[2] 2511	1,702	1	1,702	0.20 (12)	340
720.1 through 720.4 (new submissions)	[3] 2512	6,843	1	6,843	0.33 (20)	2,258
720.6 (amendments)	2512	2,477	1	2,477	0.17 (10)	421
720.6 (notices of discontinuance)	2512	232	1	232	0.10 (6)	23
720.8 (requests for confidentiality)		1	1	1	2	2
Total						3,044

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

[2] The term ''Form FDA 2511'' refers to both the paper Form FDA 2511 and online Form FDA 2511 in the online system known as the VCRP, which is available at *https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp.*

[3] The term ''Form FDA 2512'' refers to the paper Forms FDA 2512 and 2512a and online Form FDA 2512 in the online system known as the VCRP, which is available at *https://www.fda.gov/cosmetics/voluntary-cosmetic-registration-program/online-registration-voluntary-cosmetic-registration-program-vcrp.*

We base our estimate on information from cosmetic industry personnel and FDA experience entering data submitted on paper Forms FDA 2511, 2512, and 2512a into the online system. We estimate that, annually, 1,702 establishments that manufacture or package cosmetic products will each submit 1 registration on Form FDA 2511, for a total of 1,702 annual responses. Each submission is estimated to take about 0.20 hour per response for a total of 340.4 hours, rounded to 340. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 6,843 ingredient statements for new submissions on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take about 0.33 hour per response for a total of 2,258.19 hours, rounded to 2,258. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 2,477 amendments to product formulations on Forms FDA 2512 and FDA 2512a. Each submission is estimated to take about 0.17 hour per response for a total of 421.09 hours, rounded to 421. We estimate that, annually, firms that manufacture, pack, or distribute cosmetics will file 232 notices of discontinuance on Form FDA 2512. Each submission is estimated to take about 0.10 hour per response for a total of 23.2 hours, rounded to 23. We estimate that, annually, one firm will file one request for confidentiality. Each such request is estimated to take 2 hours to prepare for a total of 2 hours. Thus, the estimated total reporting burden is 3,044 hours.

Our estimated burden for the information collection reflects an overall increase of 3,044 hours and a corresponding increase of 11,255 responses. We attribute this adjustment to an increase in the number of hours and responses due to the consolidation of OMB control numbers 0910–0027 and 0910–0599. Total burden for the combined collection of information is therefore, 144,218 hours (141,174 hours from OMB control number 0910–0599 and 3,044 hours from OMB control number 0910–0027).

Dated: July 20, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–15996 Filed 7–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1648]

Pediatric Advisory Committee; Notice of Meeting; 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) announces a forthcoming public advisory committee meeting of the Pediatric Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 15, 2020, from 10 a.m. to 4:30 p.m.

ADDRESSES: Please note that due to the impact of the 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.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2020–N–1648. The docket will close on September 14, 2020. Submit either electronic or written comments on this public meeting by September 14, 2020. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 14, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 14, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before August 31, 2020, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

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, 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–2020–N–1648 for ''Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those