[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

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.'' FDA 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 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 the 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, September18, 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: Marieann Brill, Office of Pediatric Therapeutics, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993–0002, 240–402–3838, *marieann.brill@fda.hhs.gov,* 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 FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION: *Agenda:* The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On September 15, 2020, the Pediatric Advisory Committee (PAC) will discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act of 2003 (Pub. L. 108–155).

The PAC will meet to discuss the following products (listed by FDA Center):

(1) Center for Biologics Evaluation and Research

a. GAMUNEX®-C (immune globulin intravenous (human)), 10%, Caprylate/Chromatography Purified

(2) Center for Devices and Radiological Health

a. FLOURISH™ Pediatric Esophageal Atresia Device (humanitarian device exemption)

(3) Center for Drug Evaluation and Research

a. ADZENYS ER (amphetamine) extended-release oral suspension,

b. MYDAYIS (mixed salts of a single-entity amphetamine product) extended-release capsule, for oral use,

c. ORENCIA (abatacept) for injection, for intravenous use

d. VYVANSE® (lisdexamfetamine dimesylate) capsule and chewable tablet,

FDA will discuss acute dystonia associated with the use of attention deficit hyperactivity disorder (ADHD) medications (including methylphenidate products, amphetamine products, and atomoxetine). Additionally, FDA will discuss acute hyperkinetic movement disorder associated with the combined use of ADHD stimulants and antipsychotics (including first-generation antipsychotics and second-generation antipsychotics).

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 at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 8, 2020. Oral presentations from the public will be scheduled between approximately 10:30 a.m. and 11:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit 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 August 31, 2020. 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 September 1, 2020.

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 accommodate persons with disabilities. If you require accommodations due to a disability, please contact Marieann Brill (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 17, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–15998 Filed 7–22–20; 8:45 am]

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