

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Administration for Children and Families**

[OMB No.: 0970-0466]

**Submission for OMB Review; Comment Request**

*Title:* Initial Medical Exam Form and Initial Dental Exam Form.

*Description:* The Administration for Children and Families' Office of Refugee Resettlement (ORR) places unaccompanied minors in their custody in licensed care provider facilities until reunification with a qualified sponsor. Care provider facilities are required to provide children with services such as

classroom education, mental health services, and health care. Pursuant to Exhibit 1, part A.2 of the *Flores* Settlement Agreement (*Jenny Lisette Flores, et al. v. Janet Reno, Attorney General of the United States, et al.*, Case No. CV 85-4544-RJK (C.D. Cal. 1996), care provider facilities, on behalf of ORR, shall arrange for appropriate routine medical and dental care and emergency health care services, including a complete medical examination and screening for infectious diseases within 48 hours of admission, excluding weekends and holidays, unless the minor was recently examined at another facility; appropriate immunizations in accordance with the U.S. Public Health Service (PHS), Center for Disease

Control; administration of prescribed medication and special diets; appropriate mental health interventions when necessary for each minor in their care.

The forms are to be used as worksheets for clinicians, medical staff, and health departments to compile information that would otherwise have been collected during the initial medical or dental exam. Once completed, the forms will be given to shelter staff for data entry into ORR's secure, electronic data repository known as 'The UAC Portal'. Data will be used to record UC health on admission and for case management of any identified illnesses/conditions.

*Respondents:* Office of Refugee Resettlement Grantee staff.

**ANNUAL BURDEN ESTIMATES**

| Instrument   | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form) ..... | 150                   | 297                                | 0.20                              | 8,910              |
| Initial Dental Exam Form .....   | 150                   | 30                                 | 0.07                              | 315                |

*Estimated Total Annual Burden Hours:* 9,225.

**ESTIMATED RESPONDENT BURDEN FOR RECORDKEEPING**

| Instrument   | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|--|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Initial Medical Exam Form (including Appendix A: Supplemental TB Screening Form) ..... | 150                   | 297                                | 0.08                              | 3,564              |
| Initial Dental Exam Form .....   | 150                   | 30                                 | 0.08                              | 360                |

*Estimated Total Annual Burden:* 3,924.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov).

*OMB Comment:* OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office

of Management and Budget, Paperwork Reduction Project, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2018-19709 Filed 9-10-18; 8:45 am]

**BILLING CODE 4184-45-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. FDA-2018-N-3223]

**Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management 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 Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory

Committee. The general function of the committees 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 October 17, 2018, from 8 a.m. to 5 p.m.

**ADDRESSES:** Bethesda Marriott, 5151 Pooks Hill Rd., the Grand Ballroom, Bethesda, MD 20814. The conference center's telephone number is 301-897-9400. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>. Information about the Bethesda Marriott can be accessed at: <https://www.marriott.com/hotels/travel/wasbt-bethesda-marriott/>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2018-N-3223. The docket will close on October 16, 2018. Submit either electronic or written comments on this public meeting by October 16, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 16, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of October 16, 2018. 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 October 9, 2018, will be provided to the committees. Comments received after that date will be taken into consideration by FDA.

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-2018-N-3223 for "Joint Meeting of the Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see the **ADDRESSES** section), 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.

- **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, 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.

**FOR FURTHER INFORMATION CONTACT:** Jay R. Fajiculay, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, Fax: 301-847-8533, email: [GIDAC@fda.hhs.gov](mailto:GIDAC@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 committees will discuss supplemental new drug application (sNDA) 021200, supplement 015, for ZELNORM (tegaserod maleate) tablets for oral administration, submitted by Sloan Pharma S.à.r.l, Bertrange, Cham Branch, proposed for the treatment of women with irritable bowel syndrome with constipation who do not have a history of cardiovascular ischemic disease, such as myocardial infarction, stroke, transient ischemic attack, or angina, and who do not have more than one risk factor for cardiovascular disease.

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 committees. All electronic and written submissions submitted to the Docket (see the **ADDRESSES** section) on or before October 9, 2018, will be provided to the committees. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.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 October 1, 2018. 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 October 2, 2018.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at [fdaoma@fda.hhs.gov](mailto: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 Jay Fajiculay (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: September 4, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018-19669 Filed 9-10-18; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2018-N-0055]

#### Gastrointestinal Drugs 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 Gastrointestinal Drugs 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 October 18, 2018, from 8 a.m. to 5 p.m.

**ADDRESSES:** Bethesda Marriott, 5151 Pooks Hill Rd., the Grand Ballroom, Bethesda, MD 20814. The conference center's telephone number is 301-897-9400. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>. Information about the Bethesda Marriott can be accessed at: <https://www.marriott.com/hotels/travel/wasbt-bethesda-marriott/>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2018-N-0055. The docket will close on October 16, 2018. Submit either electronic or written comments on this public meeting by October 16, 2018. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 16, 2018. The <https://www.regulations.gov> electronic filing

system will accept comments until midnight Eastern Time at the end of October 16, 2018. 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 October 9, 2018, will be provided to the committee. Comments received after that date will be taken into consideration by FDA.

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-2018-N-0055 for "Gastrointestinal Drugs Advisory Committee; Notice of Meeting; Establishment of a Public