9.2.4.8 Authorized Persons To Pick Up Child

Children may only be released to adults authorized by parents or legal guardians and whose identity has been verified by photo identification. Names, addresses, and telephone numbers of persons authorized to take a child under care out of the facility should be obtained during the enrollment process and regularly reviewed, along with clarification/documentation of any custody issues/court orders. The legal guardian(s) of the child should be established and documented at this time.

9.4.1.12 Record of Valid License, Certificate, or Registration of Facility

Every facility should hold a valid license, certificate, or documentation of registration prior to operation as required by the local and/or state statute.

9.4.2.1 Contents of Child Records

Programs should maintain a confidential file for each child in one central location on-site and should be immediately available to the child's caregivers/teachers (who should have parental/guardian consent for access to records), the child's parents/guardians, and the licensing authority upon request. The file for each child should include the following:

(a) Pre-admission enrollment information;

(b) Admission agreement signed by the parent/guardian at enrollment;

(c) Initial and updated health care assessments, completed and signed by the child's primary care provider, based on the child's most recent well care visit;

(d) Health history completed by the parent/guardian at admission;

(e) Medication record;

(f) Authorization form for emergency medical care;

(g) Written informed consent forms signed by the parent/guardian allowing the facility to share the child's health records with other service providers.

10.4.2.1 Frequency of Inspections for Child Care Centers, Large Family Child Care Homes, and Small Family Child Care Homes

The licensing inspector or monitoring staff should make an onsite inspection to measure compliance with licensing/regulatory rules prior to issuing an initial license and at least two inspections each year to each center and large and small family child care home thereafter. At least one of the inspections should be unannounced, and more if they are needed for the facility to achieve satisfactory compliance or if the facility is closed at any time. Sufficient numbers of licensing inspectors should be hired to provide adequate time visiting and inspecting programs to ensure compliance with regulations.

The number of inspections should not include those inspections conducted for the purpose of investigating complaints. Complaints should be investigated promptly, based on severity of the complaint. States are encouraged to post the results of licensing inspections, including complaints, on the Internet for parent and public review. Parents/guardians should be provided easy access to the licensing rules and made aware of how to report complaints to the licensing agency.

Dated: December 12, 2014.

Linda K. Smith,

Deputy Assistant Secretary for Early Childhood Development, Administration for Children and Families, U.S. Department of Health and Human Services.

[FR Doc. 2014–29649 Filed 12–17–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0996]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review

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: Fax written comments on the collection of information by January 20, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0389. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Guidance for Industry: Fast Track Drug Development Programs: Designation, Development, and Application Review—(OMB Control Number 0910–0389)—Extension

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 506 (21 U.S.C. 356). The section authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to address an unmet medical need. Under section 112(b) of FDAMA, FDA issued guidance to industry on fast track policies and procedures outlined in section 506 of the FD&C Act. The guidance discusses collections of information that are specified under section 506 of the FD&C Act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. The guidance describes three general areas involving the collection of information: (1) Fast track designation requests, (2) premeeting packages, and (3) requests to submit portions of an application. Of these, fast track designation requests and premeeting packages, in support of receiving a fast track program benefit, provide for additional collections of information not covered elsewhere in statute or regulation. Information in support of fast track designation or fast track program benefits that has previously been submitted to the Agency, may, in some cases, be incorporated into the request by referring to the information rather than resubmitting it.

Under section 506(a)(1) of the FD&C Act, an applicant who seeks fast track designation is required to submit a request to the Agency showing that the drug product: (1) Is intended for a serious or life-threatening condition and (2) has the potential to address an

unmet medical need. The Agency expects that information to support a designation request will have been gathered under existing provisions of the FD&C Act, the PHS Act, or the implementing regulations. If such information has already been submitted to the Agency, the information may be summarized in the fast track designation request. The guidance recommends that a designation request include, where applicable, additional information not specified elsewhere by statute or regulation. For example, additional information may be needed to show that a product has the potential to address an unmet medical need where an approved therapy exists for the serious or life-threatening condition to be treated. Such information may include clinical data, published reports, summaries of data and reports, and a list of references. The amount of information and discussion in a designation request need not be voluminous, but it should be sufficient to permit a reviewer to assess whether the criteria for fast track designation have been met.

After the Agency makes a fast track designation, a sponsor or applicant may submit a premeeting package that may include additional information supporting a request to participate in certain fast track programs. The premeeting package serves as background information for the meeting and should support the intended objectives of the meeting. As with the request for fast track designation, the Agency expects that most sponsors or applicants will have gathered such information to meet existing requirements under the FD&C Act, the PHS Act, or implementing regulations. These may include descriptions of clinical safety and efficacy trials not conducted under an investigational new drug application (*i.e.,* foreign studies) and information to support a request for accelerated approval. If such information has already been submitted to FDA, the information may be summarized in the premeeting package. Consequently, FDA anticipates that the additional collection of information attributed solely to the guidance will be minimal.

Under section 506(c) of the FD&C Act, a sponsor must submit sufficient clinical data for the Agency to determine, after preliminary evaluation, that a fast track product may be effective. Section 506(c) also requires that an applicant provide a schedule for the submission of information necessary to make the application complete before FDA can commence its review. The guidance does not provide for any new collection of information regarding the submission of portions of an application that are not required under section 506(c) of the FD&C Act or any other provision of the FD&C Act.

All forms referred to in the guidance have current OMB approval: Forms FDA 1571 (OMB control number 0910–0014), 356h (OMB control number 0910–0338), and 3397 (OMB control number 0910–0297).

Respondents to this information collection are sponsors and applicants who seek fast track designation under section 506 of the FD&C Act. The Agency estimates the total annual number of respondents submitting requests for fast track designation to the Center for Biologics Evaluation and Research and the Center for Drug Evaluation and Research is approximately 81, and the number of requests received is approximately 115 annually. FDA estimates that the number of hours needed to prepare a request for fast track designation is approximately 60 hours per request.

Not all requests for fast track designation may meet the statutory standard. Of the requests for fast track designation made per year, the Agency granted approximately 100 requests from 81 respondents, and for each of these granted requests a premeeting package was submitted to the Agency. FDA estimates that the preparation hours are approximately 100 hours per premeeting package.

In the **Federal Register** of August 1, 2014 (79 FR 44780), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Guidance for industry: Fast track drug development programs: Designation, development, and application review	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Designation Requests	81	1.42	115	60	6,900
Premeeting Packages	81	1.09	88	100	8,800
Total					15,700

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

Dated: December 12, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29607 Filed 12–17–14; 8:45 am]

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