

information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or

other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Uniform Project Description (UPD) Program Narrative Format for Discretionary Grant Application Forms.
OMB No.: 0970-0139.
Description: The proposed information collection would renew the Administration for Children and Families (ACF) Uniform Project Description (UPD). The UPD provides a

uniform grant application format for applicants to submit project information in response to ACF discretionary funding opportunity announcements. ACF uses this information, along with other OMB-approved information collections (Standard Forms), to evaluate and rank applications. Use of the UPD helps to protect the integrity of ACF's award selection process. All ACF discretionary grant programs are required to use this application format. The application consists of general information and instructions; the Standard Form 424 series, which requests basic information, budget information, and assurances; the Project Description that requests the applicant to describe how program objectives will be achieved; and other assurances and certifications. Guidance for the content of information requested in the Uniform Project Description is based in 45 CFR 75.203, 75.204, and 45 CFR part 75, Appendix I.

Respondents: Applicants to ACF Discretionary Funding Opportunity Announcements.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF Uniform Project Description (UPD)	4,562	1	60	273,720

Estimated Total Annual Burden Hours: 273,720.

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.

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, Attn:

Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-3438]

Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.
ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled

“Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use.” This guidance has been developed to provide industry with FDA's recommendations on the selection of appropriate package type terms and selection of appropriate discard statements for injectable medical products for human use, packaged in multiple-dose, single-dose, and single-patient-use containers. This guidance provides FDA's revised definitions for single-dose and multiple-dose containers, and introduces the definition of a new package type term, “single-patient-use” container. Marketing applications for such products include: New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Biologics License Applications (BLAs), Premarket Approval Applications (PMAs), and Premarket Notifications under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR