intended use claim, and enhance and encourage pediatric device development programs.

This guidance does not change the regulatory threshold for valid scientific evidence. Instead, the document seeks to provide clarity and predictability for device sponsors and to ensure consistency within FDA regarding the specific criteria that should be considered when deciding whether leveraging existing clinical data to support pediatric claims is appropriate, and if so, to what extent. When considering extrapolation, sponsors are encouraged to engage FDA early in product development planning.

For the purposes of this document, ''extrapolation'' refers to the leveraging process whereby an indication for use of a device in a new pediatric patient population can be supported by existing clinical data from a studied patient population. That is, when existing data are relevant to a pediatric indication and determined to be valid scientific evidence, it may be scientifically appropriate to attempt to extrapolate such data to a pediatric use in support of demonstrating a reasonable assurance of effectiveness or probable benefit and, occasionally, safety.

FDA published in the **Federal Register** of May 6, 2015 (80 FR 26061), the document entitled ''Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices; Guidance for Industry and Food and Drug Administration Staff'' and the comment period closed on August 4, 2015. FDA has considered all of the comments received in finalizing this guidance. The comments from the docket sought further clarification of the scope of the document, the extent of extrapolation that may be feasible across various pediatric subpopulations, and the concept of ''borrowing strength'' from existing adult data. Accordingly, this guidance document has been updated to include de novo requests within the scope and to provide additional explanation on the concepts of extrapolation of data across pediatric subpopulations and ''borrowing strength.''

This guidance should be used in conjunction with other device-specific guidances to help ensure that medical devices intended for use in pediatric population provide reasonable assurance of safety and effectiveness.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the extrapolation of data for pediatric uses of medical devices. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm* or *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1827 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485 (medical device labeling); the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078 (investigational device exemptions); the collections of information in 21 CFR part 814 have been approved under OMB control number 0910–0231 (subparts A through E, premarket approval).

V. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *http://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA guidance entitled ''Premarket Assessment of Pediatric Medical Devices,'' March 24, 2014, available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089740.htm.*

Dated: June 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14640 Filed 6–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0977]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

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 July 21, 2016.

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 0910–0312. 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.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco To Protect Children and Adolescents OMB Control Number 0910–0312—Extension

This is a request for an extension of OMB approval for the information collection requirements contained in FDA's regulations for cigarettes and smokeless tobacco containing nicotine. The regulations that are codified at 21 CFR part 1140 are authorized by section 102 of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31). Section 102 of the Tobacco Control Act required FDA to publish a final rule regarding cigarettes and smokeless tobacco identical in its provisions to the regulation issued by FDA in 1996 (61 FR 44396, August 28, 1996), with certain specified exceptions including that subpart C (which included 21 CFR 897.24) and 897.32(c) be removed from the reissued rule (section 102(a)(2)(B)). The reissued final rule was published in the **Federal Register** of March 19, 2010 (75 FR 13225).

This collection includes reporting information requirements for § 1140.30 which directs persons to notify FDA if they intend to use a form of advertising that is not addressed in the regulations. The requirements are as follows:

§ 1140.30	Reporting	Directs persons to notify FDA if they intend to use a form of advertising that is not originally described in the March 19, 2010, final rule.

In the **Federal Register** of January 12, 2016 (81 FR 1428), 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]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1140.30—Scope of Permissible Forms of Labeling and Advertising	300	1	300	1	300

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

The burden hour estimates for this collection of information were based on industry-prepared data and information regarding cigarette and smokeless tobacco product advertising expenditures.

Section 1140.30 requires manufacturers, distributors, and retailers: (1) To observe certain format and content requirements for labeling and advertising and (2) to notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in § 1140.30 is sufficiently broad to encompass most forms of advertising. FDA estimates that approximately 300 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice. Therefore, FDA estimates that the total time required for this collection of information is 300 hours.

Dated: June 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–14628 Filed 6–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than August 22, 2016.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N–39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Children's Hospitals Graduate Medical Education Payment Program Application and Full-Time Equivalent Resident Assessment Forms OMB No. 0915–0247 Revision.

Abstract: The Children's Hospitals Graduate Medical Education (CHGME) Payment Program was enacted by Public Law 106–129, and reauthorized by the CHGME Support Reauthorization Act of 2013 (Pub. L. 113–98) to provide Federal support for graduate medical education (GME) to freestanding children's hospitals. The legislation indicates that eligible children's hospitals will receive payments for both direct and indirect medical education. The CHGME Payment Program application and full-time equivalent (FTE) resident assessment forms received OMB clearance on June 30, 2014.

The CHGME Support Reauthorization Act of 2013 included a provision to