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

Dated: November 1, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 96–28592 Filed 11–3–96; 8:45 am]

BILLING CODE 4184–01–M

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care Biannual Aggregate Report.

OMB No.: New Collection.

Description: This legislatively mandated report collects program and participant's data on all children and families receiving direct CCDF services. Aggregate data will be collected and will be used to determine the scope, type, and methods of child care delivery, and to provide a report to Congress.

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–800	54	2	40	4,320

Estimated Total Annual Burden Hours: 4,320

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the 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 Information Services, Division of Information Resource Management Services, 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.

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.

Dated: November 1, 1996.

Bob Sargis,

Acting Reports Clearance Officer.

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Food and Drug Administration

[Docket No. 96N–0249]

Applications for Exemption From Preemption of State and Local Requirements Pertaining to the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is inviting State and local governments to file applications for exemption from preemption for requirements governing the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents. FDA's regulations provide that the agency may, under certain conditions, exempt a State or local requirement from preemption. This action is intended to ensure that the objectives of the final rule pertaining to the sale and distribution of cigarettes and smokeless tobacco to children and adolescents are reached. In order to facilitate and expedite review of these applications for exemption from preemption, FDA will consider the applications in two separate groups. The two groups are based on the effective dates for different requirements under the final rule. State and local governments seeking exemption from preemption must submit a separate application for each of the two groups. In determining whether to grant or deny exemptions for submitted applications, FDA intends to consolidate all of the applications within each group and to use a separate proceeding for each of the two groups.

DATES: Submit applications for group 1 (i.e., requirements that are different from or in addition to requirements under 21 CFR 897.14(a) and (b)) by December 9, 1996; submit applications for Group 2 (i.e., requirements that are different from or in addition to all other requirements in 21 CFR part 897) by May 6, 1997.

ADDRESSES: Applications to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Background

Under section 521(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360k(a)), any State or local requirement applicable to a device is preempted if such requirement: (1) Is different from, or in addition to, any requirement applicable under the act to the device; and (2) relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

In implementing section 521 of the act, FDA has historically interpreted that provision narrowly and has found it to have preemptive effect only for those State and local requirements that, in fact, clearly impose specific requirements with respect to specific devices that are manifestly in addition to analogous Federal requirements (see § 808.1(d) (21 CFR 808.1(d))). In addition, section 521 of the act ''does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act'' (§ 808.1(d)(2)).

In the Federal Register of August 28, 1996 (61 FR 44396), FDA issued a final rule (the final rule) governing the sale and distribution of nicotine-containing