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.

[FR Doc. 96–28593 Filed 11–3–96; 8:45 am]

BILLING CODE 4184–01–M

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

cigarettes and smokeless tobacco in order to protect children and adolescents. FDA has determined that cigarettes and smokeless tobacco are nicotine-delivery devices under the act. The final rule will become effective on August 28, 1997, except for the following sections: (1) Section 897.14(a) (21 CFR 897.14(a)), which prohibits sales of cigarettes or smokeless tobacco to any person younger than 18 years of age, will become effective on February 28, 1997; (2) § 897.14(b), which requires retailers to verify that purchasers of cigarettes and smokeless tobacco are at least 18 years old, will become effective on February 28, 1997; and (3) § 897.34(c), which places certain restrictions on event sponsorships, will become effective on August 28, 1998. Once a requirement under the final rule becomes effective, analogous State and local requirements that are different from, or in addition to, that requirement will be preempted under section 521(a) of the act.

The agency's assertion of jurisdiction over cigarettes and smokeless tobacco does not preclude State or local requirements other than those expressly preempted by section 521(a) of the act. Moreover, State and local requirements that are preempted by the final rule may be exempted from preemption in accordance with section 521(b) of the act and its implementing regulations (part 808 (21 CFR part 808)).

II. Exemptions from Preemption

Section 521(b) of the act and its implementing regulations provide that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a State or local requirement from preemption under such conditions as the Commissioner of Food and Drugs (the Commissioner) may prescribe if the State or local requirement is: (1) More stringent than a requirement under the act that would be applicable to the device if an exemption were not in effect; or (2) required by compelling local conditions, and compliance with the State or local requirement would not cause the device to be in violation of any requirement applicable under the act.

In this document and consistent with the final rule, FDA is inviting all State and local governments to submit applications to exempt from preemption those State or local requirements pertaining to cigarettes or smokeless tobacco that are preempted by the agency's final rule. Under § 808.25(g), State or local requirements pertaining to cigarettes or smokeless tobacco may be exempted from preemption under section 521(b) of the act if the State or local requirement: (1) Meets the exemption requirements established under section 521(b) of the act; and (2) is in the best interest of public health and is consistent with the goals of the final rule. Exemptions from preemption granted by FDA apply only to preemption under section 521 of the act.

Exemptions from preemption will be granted only for those requirements that have the force and effect of law, i.e., have been enacted, promulgated, or issued in final form. However, an application may be submitted after the establishment of the statute or regulation by the State or local government, but before the effective date of the requirement. With regard to any State or local requirements that have not yet been enacted, promulgated, or issued in final form, any State, political subdivision, or other interested party may seek, in accordance with § 808.5, an advisory opinion as to whether such State or local requirements would be preempted once established. To the extent that requirements are enacted, promulgated, or issued in final form in the future, and such requirements are preempted under section 521(a) of the act, State or local governments may submit applications for exemption from preemption for such requirements at that time.

III. Applications

In order to facilitate and expedite review of the applications submitted by State and local governments according to this document, FDA will consider the applications in two separate groups. The groups, which are based on the effective dates for different requirements under the final rule, are as follows:

(1) *Group 1*: State and local requirements governing the sale or distribution of cigarettes or smokeless tobacco that are different from, or in addition to, FDA requirements under § 897.14(a) and § 897.14(b) of the final rule. Section 897.14(a) prohibits retailers from selling cigarettes or smokeless tobacco to anyone younger than 18 years of age. Section 897.14(b) requires retailers (except in certain situations) to verify, by means of photographic identification containing the bearer's date of birth, that the person purchasing the product is not younger than 18 years of age. No such verification is required for any person over the age of 26.

(2) *Group 2*: State and local requirements governing the sale or distribution of cigarettes or smokeless tobacco that are different from, or in addition to, all other FDA requirements under the final rule.

State and local governments that want to file an application for exemption from preemption pursuant to this document should submit a separate application for each group. Applications for exemption from preemption for existing requirements that are preempted may be submitted now or at any time in the future. In order to be considered as part of the proceedings described in this notice, however, applications for Group 1 should be submitted by December 9, 1996 and applications for Group 2 should be submitted by May 6, 1997. Until exemptions are granted for preempted State or local requirements, the requirements may not be enforced.

Each application should be in the form of a letter to the Commissioner. The application should be identified with the docket number found in brackets in the heading of this document, as well as the group number under which exemption is being sought. An original and two copies of the application, and any accompanying material, subsequent reports, or correspondence concerning the application, should be submitted to the Dockets Management Branch (address above).

The application letter must be signed by an individual who is authorized to request the exemption on behalf of the State or local government. In the past, most exemption requests have been submitted by State Attorneys General. In some States or localities, other officials may also be authorized under State or local law to submit requests.

The envelope of the application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements. In addition, the envelope should be identified with the docket number found in brackets in the heading of this document, as well as the group number under which exemption is being sought.

The application must be accompanied by sufficient information and data to enable FDA to determine whether the requirement in question is preempted by section 521(a) of the act and, if so, whether the Commissioner should grant the exemption as provided in section 521(b) of the act. Specifically, for each requirement for which an exemption is sought, the application shall include the following information to the extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of the relevant statute, rule, regulation, or ordinance, as well as the date of enactment, promulgation, or issuance in final form.

(2) Copies of relevant background material, including any legislative history, hearing reports, or similar materials pertinent to enactment, promulgation, or issuance of the requirement, to enable the Commissioner to determine the intent behind the State or local requirement.

(3) Copies of any judicial or administrative interpretations of the State or local requirement.

(4) A comparison of the requirement of the State or political subdivision and any Federal requirements under the act or the final rule to show similarities and differences.

(5) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(6) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(a) The requirement is more stringent than a requirement applicable to cigarettes or smokeless tobacco under the act or the final rule. If the State or political subdivision relies upon this basis for exemption from preemption, the application should include information or an explanation as to how and why the requirement of the State or political subdivision is more stringent than requirements under the act or the final rule.

(b) The requirement is required by compelling local conditions, and compliance with the requirement would not cause cigarettes or smokeless tobacco to be in violation of any applicable requirement under the act or the final rule. If the State or political subdivision relies upon this basis for exemption from preemption, the application should include information or an explanation as to why compliance with the requirement of the State or political subdivision would not cause cigarettes or smokeless tobacco to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions.

(7) The title of the chief administrative or legal officers of the State or local agency that has primary responsibility for administration of the requirement.

(8) If requested by FDA, any records concerning administration of the requirement.

(9) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(10) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(11) For local requirements that have been preempted under State law, a copy of the relevant State preemptive provision and an explanation of why the local requirement is no longer preempted under State law.

IV. Procedures for Processing Applications

Because FDA anticipates that the issues raised within each group by the applications for exemption will be similar or related, the agency intends to consolidate all of the applications within each group and to use a separate proceeding for each of the two groups. FDA notes that the agency has consolidated proceedings on such matters in the past (e.g., hearing aids). The process for each consolidated proceeding will be as follows:

(1) Upon receipt of an application, FDA will evaluate the application on its own merits and the circumstances applicable to the jurisdiction submitting the application in order to determine whether to grant or deny an exemption.

(2) FDA will issue a single Federal Register document (proposed rule) for each group that will, for each applying State or local government, propose to grant or deny exemptions from preemption for existing State and local government requirements that fall within that group. At the same time, FDA will issue a notice in the Federal Register providing an opportunity to request an oral hearing. If a hearing is granted, it will cover all applications for exemption from preemption for those requirements that fall within the applicable group, and it will be conducted under FDA regulations in 21 CFR parts 15 and 808.

(3) For each group, FDA will review all written comments submitted on the proposed rule and the administrative record of the oral hearing, if an oral hearing is granted, and will publish in the Federal Register a final rule identifying each requirement for which an exemption from preemption is granted, conditionally granted, or denied.

Specific details regarding the procedures under which applications will be processed can be found in § 808.25.

Applications submitted after the applicable dates set forth in this document will be considered by FDA in the order that they are received after the agency completes the proceedings described in this document.

Dated: November 1, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–28681 Filed 11–6–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 94P–0429]

Additional Data Regarding the Composition of Conjugated Estrogens; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that additional materials have been submitted to Docket No. 94P–0429, the docket established for a citizen petition filed on November 30, 1994, on behalf of Wyeth-Ayerst Laboratories, Division of American Home Products Corp. These materials include amendments to the petition and data supporting the petition submitted by Wyeth-Ayerst as well as data submitted to the docket by FDA and other interested persons. Among the documents submitted to the docket by FDA is a document entitled ''Preliminary Analysis of Scientific Data on the Composition of Conjugated Estrogens.'' The agency is requesting comments on this document as well as on the citizen petition, amendments to the petition, and other materials in the docket.

DATES: Written comments by December 9, 1996.

ADDRESSES: Submit written requests for single copies of the document entitled ''Preliminary Analysis of Scientific Data on the Composition of Conjugated Estrogens'' to the Drug Information Branch, Division of Communications Management (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the materials submitted to the docket to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except that individuals may submit one. Requests and comments should be identified with the docket number found in brackets in the heading of this document. Materials related to the Wyeth-Ayerst citizen petition on conjugated estrogens are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Diane Sullivan-Ford, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish