

DMB

Display Date	4. 22 .99
Ex. Date	4. 23
Certifier	C. Wms - DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0803]

Agency Information Collection Activities: Proposed Collection; 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.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information concerning restrictions on the sale and distribution of cigarettes and smokeless tobacco in order to protect children and adolescents under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Submit written comments on the collection of information by *(insert date 60 days after date of publication in the Federal Register.)*

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Heather M. Rubino, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, rm. 15-74, Rockville, MD 20857, 301-827-3322.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents—OMB No. 0910-0312—Extension

Part 897 (21 CFR part 897) reflects requirements in sections 502(e)(2) and 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(e)(2) and 360j(e)).

Section 897.24 is intended to implement section 502(e)(2) of the act. Under section 502(e)(2) of the act, a device is misbranded unless its label bears the product's established name. Section 502(e)(4) of the act, in turn, explains that the "established name" with respect to a device means: (1) The applicable official name of the device designated under section 508 of the act (21 U.S.C. 358), (2) if there is no such name and the device is recognized in an official compendium, then the official title in such compendium, or (3) if neither (1) nor (2) apply, then "any common or usual name of such device." Here, no official names have been designated under section 508 of the act, and these products are not recognized in an official compendium. Consequently, FDA developed established names for these products under section 502(e)(4) of the act. Section 897.24 requires that each cigarette or smokeless tobacco product package, carton, box, or container of any kind that is offered for sale, sold, or otherwise distributed bear whichever of the following established names is appropriate: "Cigarettes," "Cigarette Tobacco," "Loose Leaf Chewing Tobacco," "Plug Chewing Tobacco," "Twist Chewing Tobacco," "Moist Snuff," or "Dry Snuff."

Section 520(e) of the act authorizes the agency to, by regulation, require that a device be restricted to sale, distribution, or use "upon such other conditions as the [agency] may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the [agency] determines that there cannot otherwise be reasonable assurance of its safety and effectiveness." In the **Federal Register** of August 28, 1996 (21 CFR 44396), the agency issued regulations restricting the sale and distribution of cigarettes and smokeless tobacco under this authority (hereinafter referred to as the August 1996 final rule).

Sections 897.30 and 897.32 are intended to help protect children and adolescents by reducing the appeal of cigarettes and smokeless tobacco to them. Section 897.30, in part, contains a comprehensive list of permissible forms of advertising and labeling; in the unlikely event that a person wishes to use a form of advertising or labeling that is not described in § 897.30, the rule directs persons to notify FDA. The rule's concept of permitted advertising is sufficiently broad

to encompass almost all known forms of advertising, but the agency has provided a reporting estimate of 1 hour in the remote chance that a firm will provide such notice to FDA.

Section 897.32 would reduce the appeal of cigarettes and smokeless tobacco to children and adolescents by requiring most advertisements to use black text on white backgrounds, without any colors or pictures. It would also require advertising to include the product's established name and a statement of its intended use. In the August 1996 final rule, FDA estimated that approximately 25,000 pieces of labeling or advertising will be submitted to the agency under this provision. The agency arrived at this estimate by comparing the advertising expenditures by the cigarette and smokeless tobacco industries and by the pharmaceutical industry and the number of pieces of advertising that the agency receives from the pharmaceutical industry, and projecting that printed advertisements may increase due to the rule's effect on promotional activities (see 61 FR 44396 at 44597). FDA also estimated that the time required for such advertising is 1 hour based on the highest estimated time reported in industry comments on the proposed rule.

The text-only requirement of § 897.32 does not apply to advertisements in "adult" publications, as defined in § 897.32(a)(2). Under that definition, firms wishing to advertise in "adult" publications may need to retain records to demonstrate that the publication is an "adult" publication within the meaning of § 897.32. In the August 1996 final rule, FDA estimated that 31 respondents may be affected and that a total of 100,000 hours would be needed for such surveys (see 61 FR 44396 at 44612). The 31 respondents reflects the number of manufacturers as reported in a 1992 U.S. census of tobacco product manufacturers, and the estimated total time for these surveys would be 100,000 hours, assuming 100 surveys (for the approximately 100 magazines in which tobacco manufacturers advertise) at 1,000 hours per survey or approximately 3,226 hours per respondent.

The medical device reporting requirements (21 CFR 803.19 and 804.25) were addressed in a separate rulemaking that published in the **Federal Register** of May 12, 1998 (63 FR 26069 and 26129).

Description of Respondents: Cigarette and smokeless tobacco manufacturers, distributors, and retailers.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs
897.24	2,000	1	2,000	40	80,000	\$17 million
897.30	1	1	1	1	1	0
897.32	25,000	1	25,000	1	25,000	0
Total					105,001	\$17 million

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
897.32	31	1	31	3,226	100,000	\$2 million	\$1 million
Total					100,000	\$2 million	\$1 million

It should be noted that some information requested from respondents is already provided or possessed by the respondents. For example, § 897.24 makes “cigarettes” the established name for cigarettes, and cigarette packages already use that name. Therefore, there should not be any significant burden on respondents to comply with § 897.24.

FDA also notes that, due to ongoing litigation concerning FDA’s authority to issue regulations pertaining to cigarettes and smokeless tobacco, §§ 897.24, 897.30, and 897.32 have not become

effective. Nevertheless, FDA intends to submit the proposed collection of information to OMB for its review and clearance under the PRA so that it will continue to be able to collect the information once these provisions become effective.

Dated: April 15, 1999



William K. Hubbard
Acting Deputy Commissioner
for Policy

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

