

indicates that Snore Formula, Inc., has agreed to cease making challenged representations, and warns distributors that they may be terminated if they do not conform their representations to the requirements placed on Snore Formula, Inc. Part VII of the order requires dissemination of Attachment A to future distributors, and that Snore Formula, Inc., monitor their distributors, and terminate sales to distributors who make representations prohibited by the order.

The remainder of the proposed order contains standard requirements that proposed respondents maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements of the order; distribute copies of the order to certain company officials and employees; notify the Commission of any change in the corporation that may affect compliance under the order; notify the Commission of any change in employment by the individual proposed respondents, and file one or more reports detailing their compliance with the order. Part XIV of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

This proposed order, if issued in final form, will resolve the claims alleged in the complaint against the named respondents. It is not the Commission's

intent that acceptance of this consent agreement and issuance of a final decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

**Donald S. Clark**

*Secretary*

[FR Doc. 03-9854 Filed 4-21-03; 8:45 am]

**BILLING CODE 6750-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

**[30DAY-40-03]**

**Agency Forms Undergoing Paperwork Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these

requests, call the CDC Reports Clearance Officer at (404) 498-1210. Send written comments to CDC, Desk Officer, Human Resources and Housing Branch, New Executive Office Building, Room 10235, Washington, DC 20503. Written comments should be received within 30 days of this notice.

*Proposed Project: Application for Training (OMB No. 0920-0017)—Revision—*The Public Health Practice Program Office (PHPPO), in conjunction with the Public Health Training, offers self-study, computer-based training, satellite broadcasts, video courses, webcasts, instructor-led field courses, and lab courses related to public health professionals worldwide. Employees of hospitals, universities, medical centers, laboratories, state and federal agencies, and state and local health departments apply for training in an effort to learn up-to-date public health procedures. The "Application for Training" forms are the official applications used for all training activities conducted by the CDC. The Continuing Education (CE) Program includes CDC's accreditation to provide Continuing Medical Education (CME), Continuing Nurse Education (CNE), Certified Health Education Specialist (CHES), and Continuing Education Unit (CEU) for almost all training activities.

The estimated annualized burden is 2,548 hours.

Respondents	Number of respondents	Number of responses/respondent	Average burden/response (in hours)
National Laboratory Training Network Registration Form, Training Form 32.1 .....	8,500	1	5/60
Registration for Training and Continuing Education, Form 36.5 .....	20,000	1	5/60
Management for International Public Health Course Application Form .....	25	1	15/60
Student Information Form .....	5,000	1	2/60

Dated: April 16, 2003.

**Thomas A. Bartenfeld,**

*Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.*

[FR Doc. 03-9858 Filed 4-21-03; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title: Child Care and Development Fund Plan for States/Territories.*

*OMB No.: 0970-0114.*

*Description:* The Child Care and Development Fund (CCDF) Plan for States and Territories is required from the Child Care Lead Agency by section 658E of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101-508), 42 U.S.C. 9858. The implementing regulations for the statutorily required Plan are at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF-118, is required biennially and remains in effect for two years. This Plan, provides ACF and the public with a description of, and assurance about, the State's child care program. The ACF-118 is approved through February 29, 2004 making it available to States and Territories

needing to submit Amendments through the end of the FY 2003 Plan Period. However, in July 2003, States and Territories will be required to submit their FY 2004-2005 Plans. Consistent with the statute and regulations, ACF requests extension of the ACF-118 with minor corrections and modifications. The Tribal Plan (ACF-118A) is not affected by this notice.

*Respondents:* State and Territorial Lead Agencies.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-118 .....	56	.5	162.57	4,552

*Estimated Total Annual Burden Hours:* 4,552.

*Additional Information:* Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

*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, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: April 15, 2003.

**Bob Sargis,**

*Reports Clearance Officer.*

[FR Doc. 03-9832 Filed 4-21-03; 8:45 am]

BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03D-0141]

#### **Guidance for Industry and FDA; Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA." This guidance document describes a means by which optical

impression systems for the computer assisted design and manufacturing CAD/CAM of dental restorations may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to exempt the type device from premarket notification requirements and establish this guidance document as the special control for the type device. This guidance document is immediately in effect as the special control for optical impression systems for CAD/CAM, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "Class II Special Controls Guidance Document: Optical Impression Systems for Computer Assisted Design and Manufacturing (CAD/CAM) of Dental Restorations; Guidance for Industry and FDA" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:** Kevin Mulry, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-827-5283, ext. 185.

**SUPPLEMENTARY INFORMATION:**

### I. Background

The guidance provides FDA's recommendations to manufacturers for evaluating and labeling optical impression systems for CAD/CAM of dental restorations. An optical impression system for CAD/CAM of dental restorations is a device used to record the topographical characteristics of teeth, dental impressions, or stone models by analog or digital methods for use in the computer assisted design and manufacturing of dental restorative prosthetic devices. Such systems may consist of a camera, scanner or equivalent type of sensor and a computer with software.

Following the effective date of the final rule exempting this type of device, manufacturers of optical impression systems for CAD/CAM of dental restorations will need to address the issues covered in this special control guidance. However, the manufacturer need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule exempting optical impression systems for CAD/CAM of dental restorations from the premarket notification requirements under section 510(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(m)) and establishing this guidance document as the special control for the device.

Section 510(m)(2) of the act provides that 1 day after the date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative, or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.