significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AEA VA E5 Galax, VA [Revised]

Twin County Airport, VA
(lat. 36°45′58″ N, long. 80°49′25″ W)
Pulaski VORTAC
(lat. 37°05′16″ N, long. 80°42′46″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Twin County Airport and within 4 miles each side of the Pulaski VORTAC 194° radial extending from the 6.3-mile radius to 7 miles south of the VORTAC and within 4 miles each side of the 179° bearing from the airport extending from the 6.3-mile radius to 12 miles south of the airport.

* * * * *

Issued in Jamaica, New York on January 8, 1997.

James K. Buckles,

Acting Manager, Air Traffic Division, Eastern Region.

[FR Doc. 97–1400 Filed 1–17–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 95N–0033]

Dental Devices; Endodontic Dry Heat Sterilizer

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the endodontic dry heat sterilizer, a medical device. Commercial distribution of this device must cease, unless a manufacturer or importer has filed with FDA a PMA or a notice of completion of a PDP for its version of the endodontic dry heat sterilizer within 90 days of the effective date of this regulation. This regulation reflects FDA's exercise of its discretion to require a PMA or notice of completion of a PDP for the preamendments device.

EFFECTIVE DATE: January 21, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of August 12, 1987 (52 FR 30082), FDA issued a final rule classifying the endodontic dry heat sterilizer (§ 872.6730 (21 CFR 872.6730)) into class III (premarket approval). Section 872.6730 applies to: (1) Any endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976, the date of enactment of the Medical Devices Amendments of 1976 (Pub L. 94–295), and (2) any device that FDA has found to be substantially equivalent to the endodontic heat sterilizer and that has been marketed on or after May 28, 1976.

In the Federal Register of December 30, 1980 (45 FR 86155), FDA published the recommendation of the Dental Device Classification Panel (the panel), of the Medical Devices Advisory Committee, an FDA advisory committee, regarding the classification of the device.

The panel recommended that the device be in class III (premarket approval) because the device presented an unreasonable risk of illness or injury. According to the panel, the devices failed to sterilize adequately various endodontic and dental instruments. The panel felt that the failures could be the result of: (1) The device not reaching and maintaining an adequate temperature because of a faulty thermostat or (2) the result of unequal heat distribution by the glass beads throughout the well despite sufficient heat. The panel believed that it was not possible to establish an adequate performance standard for the device because satisfactory performance had never been demonstrated. The panel recommended the device to be subject to premarket approval to ensure that manufacturers of the device demonstrate satisfactory performance and that further study was necessary to determine the causes of the device's ineffectiveness.

FDA agreed with the panel's recommendation that endodontic dry heat sterilizers be classified into class III. FDA believed that there was an unreasonable risk of illness or injury because of the potential failure of the device to sterilize dental instruments adequately. FDA believed that there was inadequate information to determine if general controls or a performance standard would provide reasonable assurance of safety and effectiveness.

In the Federal Register of June 7, 1995 (60 FR 30032), FDA published a proposed rule to require the filing under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)) of a PMA or a notice of completion of a PDP for the endodontic dry heat sterilizer. In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act, and the benefits to the public from use of the device (60 FR 30032 at 30037). The June 7, 1995, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's findings. Under section 515(b)(2)(B) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in classification of the endodontic heat sterilizer was required to be submitted by September 5, 1995. The comment period closed August 7, 1995.

FDA received one comment in response to the proposed rule. The comment recommended that the endodontic dry heat sterilizer remain classified as class III, until sufficient evidence has been submitted documenting the safety and efficacy of these devices. It also pointed out concern in the use of the endodontic dry heat sterilizer for the generalized sterilization of instruments because of marked temperature gradients within the well which could result in inadequate sterilization and the appropriate use of the devices to sterilize large bulk instruments. FDA agrees with the concern and the comment that a PMA be required for endodontic dry heat sterilizers.

II. Findings With Respect to Risks and Benefits

A. Degree of Risk

The primary risk to health is infection through the use of inadequately sterilized instruments. A review of the literature has identified the following problems associated with the use of endodontic dry heat sterilizers which can contribute to the inability of these devices to sterilize instruments, including general medical instruments.

1. Temperature Variations Within the Well.

There are many reports in the literature describing the temperature variations found within the wells of endodontic dry heat (glass bead) sterilizers. It has been reported that the temperature distribution in four brands of these devices at two different sites from the center and at six different depths in the well varied significantly depending upon location. The temperature was highest at a location which was closest to the wall and midway down from the surface. Furthermore data have demonstrated temperature variations as much as 10 °C over time near the periphery of the well. The information in the literature suggested that endodontic dry heat (glass bead) sterilizers should not be used as a substitute for dry heat convection or steam sterilization sterilizers because of the temperature variations.

2. Exposure Times for the Sterilization of Instruments.

The manufacturers' recommended exposure times for sterilization of instruments vary from as short as 2 seconds to 45 seconds for sterilizers whose purported operating temperatures were from 218 to 260 °C. However, location in the well, size and mass, number and shape of the instruments must be factored into the amount of time required for sterilization. Larger instruments composed of more metal take more time to heat than smaller instruments. It was reported that the time required to raise an instrument's temperature was dependent upon its size. Small instruments such as root canal files heated rapidly while large instruments such as cotton pliers never reached the specified operating temperature. Endodontic dry heat (glass bead) sterilizers have been reported to be effective only with small instruments that can be imbedded into the heat transfer media and that their effectiveness has not been demonstrated for instruments of larger bulk. The insertion of large instruments would reduce the temperature of the glass beads below the minimum temperature required for sterilization. Heat conduction in a large, partially imbedded device would be variable.

Precleaning of the instruments before insertion into the heat transfer medium in the well of the sterilizer is critical to the effectiveness of the device. It was reported that if endodontic instruments were contaminated with a protein load (blood), the time required for sterilization was more than doubled. Such adverse conditions can easily be found in infected or gangrenous pulp. There are reports that spores, which are more resistant to sterilization processes than vegetative organisms, have been found in the oral cavity and cultured from pulp material.

3. Lack of Methods to Monitor the Performance/Sterilization Efficacy of the Device.

There are no identified methods for the routine monitoring of the sterilization efficacy of the endodontic dry heat sterilizer such as the ones which exist with the traditional sterilization methods, i.e., steam autoclaves, hot air dry heat sterilizers, or ethylene oxide sterilizers. Chemical and biological indicators are available for routine monitoring of the efficacy of the cycle parameters and for the validation of the process specifications for these traditional sterilizers. The data in the literature, as noted above, suggest that the user can not be assured that instruments inserted into an endodontic dry heat sterilizer will be reliably exposed to the minimum cycle parameters required for sterilization, i.e., exposure of the device to the set temperature for the specified time.

4. Warm–up Times for Endodontic Dry Heat (Glass Bead) Sterilizers.

Reported warm–up times for these devices range from 15 minutes to 50 minutes with the average of 15–20 minutes. However, it has been reported that it took up to 30 minutes for the temperature of the glass beads to stabilize even though the manufacturer claimed that the device reached operating temperature within 10 minutes.

5. Maintenance of Sterility After Removal From the Device.

The instructions for use for most of the devices do not instruct the user on the proper procedure to remove instruments from the device and how to maintain sterility of the instruments or the processed portion of the instrument during the cool down period. Because of the temperature variations reported within the wells, there exists the possibility that heat resistant microorganisms could survive on the glass beads in the cooler regions near the top of the glass beads and contaminate the instruments as they are removed from the well. Since endodontic dry heat sterilizers only process that portion of the instrument which has been inserted into the glass beads, there is also the potential of contaminating a sterile field with a device which had not been properly processed.

6. Heat Transfer Medium Remaining Upon the Devices.

Occasionally the heat transfer medium has been observed to adhere to wet instruments. If the particles are not detected before the devices are inserted into the site, then they could cause blockage of the wound site. This would cause significant problems if the heat transfer media were glass beads or molten metal.

B. Benefit of the Device

The endodontic dry heat sterilizer is used to decontaminate endodontic instruments during a procedure on a single patient provided the instruments are properly cleaned to remove organic debris before insertion into the unit. In theory the number of microorganisms that would be introduced into the same site or into a new site on the same patient during a single procedure would be reduced. Once the procedure is over, the instruments should be processed using traditional methods of decontamination and sterilization before use in the next patient.

C. Discussion of Risks and Benefits

The data in the literature indicate a lack of uniform sterilization parameters among the various endodontic dry heat (glass bead) sterilizers which have been marketed. Because of the temperature variations found within the wells of glass bead sterilizers, exposure of an instrument to an adequate sterilizing temperature is difficult to determine and must be confirmed independently for each instrument. Also determination of the sterilization exposure time is dependent upon instrument size and mass. It has been reported that some instruments never reach the appropriate temperature because of their size and mass; and that endodontic dry heat sterilizers are not appropriate for large bulk instruments.

Review of the claims being made for these devices suggests that manufacturers are expanding the claims beyond those originally defined in § 872.6730. The claims have been expanded to include the sterilization of general medical instruments and electrolysis and acupuncture needles, and to devices not regulated by FDA such as manicurist's instruments. The claims imply that these devices can be used as a substitute for the traditional methods of sterilization. It has been noted in the literature that endodontic dry heat sterilizers are not sterilizers, but are decontaminating devices and that they should not be used to sterilize instruments between patients. No system exists for: (1) Monitoring the exposure of the instrument to sterilization conditions or (2) demonstrating that the sterilization exposure parameters have been achieved within the well. Only the portion of the instrument which is inserted into the heat transfer medium has the potential of being sterilized; the portion which is not inserted into the glass beads is not sterilized. The use of endodontic dry heat sterilizers with general medical instruments and with the implication as a substitute sterilization method raises serious safety and efficacy questions which the manufacturers of these devices have not adequately addressed. There is the serious risk of infection through the use of inadequately processed instruments.

III. Final Rule

Under section 515(b)(3) of the act, FDA is adopting the findings as published in the preamble to the proposed rule and is issuing this final rule to require premarket approval of the generic type of device, endodontic dry heat device, by revising § 872.6730(c).

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed with FDA within 90 days of the effective date of this regulation for any endodontic dry heat sterilizer device that was in commercial distribution before May 28, 1976, or any device that FDA has found to be substantially equivalent to such a device on or before September 5, 1995. An approved PMA or declared completed PDP is required to be in effect for any such device on or before 180 days after FDA files the application. Any other endodontic dry heat sterilizer device that was not in commercial distribution before May 28, 1976, or that FDA has not found, on or before September 5, 1995, to be substantially equivalent to an endodontic dry heat sterilizer device that was in commercial distribution before May 28, 1976, is required to have an approved PMA or declared completed PDP in effect before it may be marketed.

If a PMA or notice of completion of a PDP for an endodontic dry heat sterilizer device is not filed on or before September 5, 1995, that device will be deemed adulterated under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)), and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the investigational device exemption (IDE) regulations part 812 (21 CFR part 812) are met.

Under § 812.2(d) of the IDE regulations, FDA hereby stipulates that the exemptions from the IDE requirements in § 812.2(c)(1) and (c)(2) will no longer apply to clinical investigations of the endodontic dry heat sterilizer devices. Further, FDA concludes that investigational endodontic dry heat sterilizer devices are significant risk devices as defined in § 812.3(m) and advises that as of the effective date of the regulations in § 872.6730(c), requirements of the IDE regulations regarding significant risk devices will apply to any clinical investigation of an endodontic dry heat sterilizer device. For any endodontic dry heat sterilizer device that is not subject to a timely filed PMA or notice of completion of a PDP, an IDE must be in effect under § 812.20 on or before September 5, 1995, or distribution of the device for investigational purposes must cease. FDA advises all persons currently sponsoring a clinical investigation involving an endodontic dry heat sterilizer to submit an IDE application to FDA no later than August 7, 1995, to avoid the interruption of ongoing investigations.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) and (e)(4) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because for more than 10 years the manufacturers of these devices have been aware of the need to prepare PMA's for these devices, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 872 is amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 872.6730 is amended by revising paragraph (c) to read as follows:

§ 872.6730 Endodontic dry heat sterilizer.

* * * * *

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before September 5, 1995, for any endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976, or that has on or before September 5, 1995, been found to be substantially equivalent to the endodontic dry heat sterilizer that was in commercial distribution before May 28, 1976. Any other endodontic dry heat sterilizer shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated:September 18, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–1336 Filed 1–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 127–97]

Exemption of Systems of Records Under the Privacy Act

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice, Drug Enforcement Administration (DEA), is amending its Privacy Act regulations to to provide clarity and to include an additional reason for the exemption from subsection (e)(3). The additional reason will contribute to a better understanding of the need for the exemption. The revised language applies to the following systems of records as named in paragraphs (c)(1) through (c)(6): Air Intelligence Program (Justice/DEA–001), Investigative Reporting and Filing System (Justice/DEA–008), Planning and Inspection Division Records (Justice/DEA–010), Operations Files (Justice/DEA–011), Security Files (Justice/DEA–013), System to Retrieve Information from Drug Evidence (Stride/Ballistics) (Justice/DEA–014).

EFFECTIVE DATE: January 21, 1997.

FOR FURTHER INFORMATION CONTACT: Patricia E. Neely, Program Analyst (202–616–0178).

SUPPLEMENTARY INFORMATION: On October 17, 1996 (61 FR 54112), a proposed rule was published in the Federal Register with an invitation to comment. No comments were received.

This order relates to individuals rather than small business entities. Nevertheless, pursuant to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601–612, it is hereby stated that the order will not have a ''significant economic impact on a substantial number of small entities.''

List of Subjects in Part 16

Administrative Practices and Procedure, Courts, Freedom of Information Act, Government in the Sunshine Act, and the Privacy Act.

Pursuant to the authority vested in the Attorney General by 5 U.S.C. 552a and delegated to me by Attorney General Order No. 793–78, 28 CFR part 16 is amended as set forth below.

Dated: December 30, 1996.

Stephen R. Colgate,

Assistant Attorney General for Administration.

1. The authority for part 16 continues to read as follows:

Authority: 5 U.S.C. 301, 552, 552a, 552B(g), 553; 18 U.S.C. 4203(a)(1); 28 U.S.C. 509, 510, 534; 31 U.S.C. 3717, 9701.

2. 28 CFR 16.98 is amended by revising paragraph (d)(6) as follows:

§ 16.98 Exemption of the Drug Enforcement Administration (DEA)—Limited Access.

* * * * *

(d) * * *

(6) From subsection (e)(3) because the requirements thereof would constitute a serious impediment to law enforcement in that they could compromise the existence of an actual or potential confidential investigation and/or permit the record subject to speculate on the identity of a potential confidential source, and endanger the life, health or physical safety or either actual or potential confidential informants and witnesses, and of investigators/law enforcement personnel. In addition, the notification requirement of subsection (e)(3) could impede collection of that information from the record subject, making it necessary to collect the information solely from third party sources and thereby inhibiting law enforcement efforts.

* * * * *

[FR Doc. 97–1317 Filed 1–17–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Chapter V

Blocked Persons, Specially Designated Nationals, Specially Designated Terrorists, Specially Designated Narcotics Traffickers, and Blocked Vessels: Additional Designations and Removal of Four Individuals

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Amendment of final rule.

SUMMARY: The Treasury Department is adding to appendices A and B to 31 CFR chapter V the names of 57 individuals and 21 entities, and revising information concerning 58 individuals and one entity, who have been determined to play a significant role in international narcotics trafficking centered in Colombia or have been determined to be owned or controlled by, or to act for or on behalf of, other specially designated narcotics traffickers. In addition, one individual specially designated narcotics trafficker and three individuals previously designated as acting for or on behalf of Iraq are being removed from the appendices.

EFFECTIVE DATE: January 15, 1997.

FOR FURTHER INFORMATION CONTACT: Office of Foreign Assets Control, Department of the Treasury, Washington, DC 22201; tel.: 202/622–2420.

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

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