perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 216

Drugs, Pharmacy compounding, Prescription drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 216 is added to read as follows:

PART 216—PHARMACY COMPOUNDING

Subpart A—General Provisions [Reserved]

Subpart B—Compounded Drug Products

Sec.

Authority: 21 U.S.C. 351, 352, 353a, 355, and 371.

Subpart A—General Provisions [Reserved]

Subpart B—Compounded Drug Products

§ 216.23 [Reserved]

§ 216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

The following drug products were withdrawn or removed from the market because such drug products or components of such drug products were found to be unsafe or not effective. The following drug products may not be compounded under the exemptions provided by section 503A(a) of the Federal Food, Drug, and Cosmetic Act:

Adenosine phosphate: All drug products containing adenosine phosphate.

Adrenal cortex: All drug products containing adrenal cortex.

Azaribine: All drug products containing azaribine.

Benoxaprofen: All drug products containing benoxaprofen.

Bithionol: All drug products containing bithionol.

Bromfenac sodium: All drug products containing bromfenac sodium.

Butamben: All parenteral drug products containing butamben.

Camphorated oil: All drug products containing camphorated oil.

Carbetapentane citrate: All oral gel drug products containing carbetapentane citrate.

Casein, iodinated: All drug products containing iodinated casein.

Chlorhexidine gluconate: All tinctures of chlorhexidine gluconate formulated for use as a patient preoperative skin preparation.

Chlormadinone acetate: All drug products containing chlormadinone acetate.

Chloroform: All drug products containing chloroform.

Cobalt: All drug products containing cobalt salts (except radioactive forms of cobalt and its salts and cobalamin and its derivatives).

Dexfenfluramine hydrochloride: All drug products containing dexfenfluramine hydrochloride.

Diamthazole dihydrochloride: All drug products containing diamthazole dihydrochloride.

Dibromsalan: All drug products containing dibromsalan.

Diethylstilbestrol: All oral and parenteral drug products containing 25 milligrams or more of diethylstilbestrol per unit dose.

Dihydrostreptomycin sulfate: All drug products containing dihydrostreptomycin sulfate.

Dipyrone: All drug products containing dipyrone.

Encainide hydrochloride: All drug products containing encainide hydrochloride.

Fenfluramine hydrochloride: All drug products containing fenfluramine hydrochloride.

Flosequinan: All drug products containing flosequinan.

Gelatin: All intravenous drug products containing gelatin.

Glycerol, iodinated: All drug products containing iodinated glycerol.

Gonadotropin, chorionic: All drug products containing chorionic gonadotropins of animal origin.

Mepazine: All drug products containing mepazine hydrochloride or mepazine acetate.

Metabromsalan: All drug products containing metabromsalan.

Methamphetamine hydrochloride: All parenteral drug products containing methamphetamine hydrochloride.

Methapyrilene: All drug products containing methapyrilene.

Methopholine: All drug products containing methopholine.

Mibefradil dihydrochloride: All drug products containing mibefradil dihydrochloride.

Nitrofurazone: All drug products containing nitrofurazone (except topical drug products formulated for dermatalogic application).

Nomifensine maleate: All drug products containing nomifensine maleate.

Oxyphenisatin: All drug products containing oxyphenisatin.

Oxyphenisatin acetate: All drug products containing oxyphenisatin acetate.

Phenacetin: All drug products containing phenacetin.

Phenformin hydrochloride: All drug products containing phenformin hydrochloride.

Pipamazine: All drug products containing pipamazine.

Potassium arsenite: All drug products containing potassium arsenite.

Potassium chloride: All solid oral dosage form drug products containing potassium chloride that supply 100 milligrams or more of potassium per dosage unit (except for controlled-release dosage forms and those products formulated for preparation of solution prior to ingestion).

Povidone: All intravenous drug products containing povidone.

Reserpine: All oral dosage form drug products containing more than 1 milligram of reserpine.

Sparteine sulfate: All drug products containing sparteine sulfate.

Sulfadimethoxine: All drug products containing sulfadimethoxine.

Sulfathiazole: All drug products containing sulfathiazole (except those formulated for vaginal use).

Suprofen: All drug products containing suprofen (except ophthalmic solutions).

Sweet spirits of nitre: All drug products containing sweet spirits of nitre.

Temafloxacin hydrochloride: All drug products containing temafloxacin.

Terfenadine: All drug products containing terfenadine.

3,3′,4′,5-tetrachlorosalicylanilide: All drug products containing 3,3′,4′,5-tetrachlorosalicylanilide.

Tetracycline: All liquid oral drug products formulated for pediatric use containing tetracycline in a concentration greater than 25 milligrams/milliliter.

Ticrynafen: All drug products containing ticrynafen.

Tribromsalan: All drug products containing tribromsalan.

Trichloroethane: All aerosol drug products intended for inhalation containing trichloroethane.

Urethane: All drug products containing urethane.

Vinyl chloride: All aerosol drug products containing vinyl chloride.

Zirconium: All aerosol drug products containing zirconium.

Zomepirac sodium: All drug products containing zomepirac sodium.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5517 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 98N–0249]

Ear, Nose, and Throat Devices; Classification of the Nasal Dilator, the Intranasal Splint, and the Bone Particle Collector

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the nasal dilator, intranasal splint, and the bone particle collector into class I (general controls). FDA is also exempting the devices from the requirements of premarket notification. This action is taken under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

EFFECTIVE DATE: April 7, 1999.

FOR FURTHER INFORMATION CONTACT: Harry R. Sauberman, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 11, 1998 (63 FR 25794), FDA issued a proposed rule to classify the nasal dilator, the intranasal splint, and the bone particle collector into class I (general controls) and to exempt them from premarket notification procedures based on new information regarding these devices.

Interested persons were given until August 10, 1998, to comment on the proposed rule. During the comment period, FDA received one comment that raised the following three issues about the nasal dilator:

(1) The comment suggested that the intended use of the external nasal dilator be expanded to also include transient causes for breathing difficulties in addition to structural abnormalities, such as nasal congestion due to colds, allergies or vasomotor rhinitis.

FDA agrees that the intended use should be expanded to include transient causes for breathing difficulties and has revised the final rule accordingly. FDA does not believe that it is necessary, for purposes of this rule, to include in the identification of the device specific disease states or conditions for transient causes for breathing difficulties.

(2) The comment also proposed the description of the external nasal dilator be changed to ''The external nasal dilator is constructed from one or more layers of material upon which a spring material is attached, with a skin adhesive applied to adhere to the skin of the nose.''

FDA agrees that this is an appropriate description of the external nasal dilator and has revised the final rule accordingly.

(3) The comment also proposed that the risks to health for the external nasal dilator be amended to state that ''the use of the external nasal dilator presents no plausible risk of ulceration and subsequent infection of the mucous membranes and such risk would be more accurately associated only with internal nasal dilators.''

FDA agrees that the risk of possible ulceration and subsequent infection of the mucous membrane would only apply to the internal nasal dilator. This does not affect the classification of the device or the final rule in any way.

II. Conclusion

FDA has concluded that the nasal dilator, the intranasal splint, and the bone particle collector do not present unreasonable risks to the public health and that general controls would provide reasonable assurance of the safety and effectiveness of the devices. FDA also concludes that in the final rule the identification of the nasal dilator be revised to ''A nasal dilator is a device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow.'' FDA notes that the external nasal dilator is constructed from one or more layers of material upon which a spring material is attached, with a skin adhesive applied to adhere to the skin of the nose and that the potential risk to health of ulceration and subsequent infection apply only to use of the internal nasal dilator and to use of the internal dilator.

On November 21, 1997, the President signed FDAMA into law. Section 206 of FDAMA, in part, added a new section 510(l) to the act (21 U.S.C. 360(l)). Under section 501 of FDAMA, new section 510(l) became effective on February 19, 1998. New section 510(l) of the act provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury (hereafter referred to as ''reserved criteria''). FDA has determined that the devices do not meet the reserved criteria, and therefore, they are exempt from the premarket notification requirements. FDA is finalizing the classification of these devices and the exemption from premarket notification for these devices.

FDA also notes that § 874.9 *Limitations of exemptions from section 510(k) of the act* (21 CFR 874.9) requires manufacturers to submit a premarket notification of any nasal dilator, intranasal splint, or bone particle collector whose intended use is different from the intended use of any legally marketed nasal dilator, intranasal splint, or bone particle collector.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this classification 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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. As noted previously, FDA may classify devices into one of three regulatory classes according to the degree of control needed to provide reasonable assurance of safety and effectiveness. FDA is classifying these three devices into class I, the lowest level of control allowed. As unclassified devices, the devices have already been subject to the general controls of the act. Under the final rule, they will now be exempt from premarket notification. Therefore, the agency certifies that this 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.

V. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 874

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 874 is amended as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 874.3900 is added to subpart D to read as follows:

§ 874.3900 Nasal dilator.

(a) *Identification*. A nasal dilator is a device intended to provide temporary relief from transient causes of breathing difficulties resulting from structural abnormalities and/or transient causes of nasal congestion associated with reduced nasal airflow. The device decreases airway resistance and increases nasal airflow. The external nasal dilator is constructed from one or more layers of material upon which a spring material is attached, with a skin adhesive applied to adhere to the skin of the nose; it acts with a pulling action to open the nares. The internal nasal dilator is constructed from metal or plastic and is placed inside the nostrils; it acts by pushing the nostrils open or by gently pressing on the columella.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

3. Section 874.4780 is added to subpart E to read as follows:

§ 874.4780 Intranasal splint.

(a) *Identification*. An intranasal splint is intended to minimize bleeding and edema and to prevent adhesions between the septum and the nasal cavity. It is placed in the nasal cavity after surgery or trauma. The intranasal splint is constructed from plastic, silicone, or absorbent material.

(b) *Classification*. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

4. Section 874.4800 is added to subpart E to read as follows:

§ 874.4800 Bone particle collector.

(a) *Identification*. A bone particle collector is a filtering device intended to be inserted into a suction tube during the early stages of otologic surgery to collect bone particles for future use.

(b) *Classification*. Class I (general controls). The device is exempt from premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9.

Dated: March 1, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–5516 Filed 3–5–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice 3001]

Privacy Act of 1974; Implementation

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is amending its regulations by exempting portions of a record system from certain provisions of the Privacy Act of 1974, as amended (5 U.S.C. 552a). Certain portions of the Records of the Office of White House Liaison (STATE–34) are exempted from 5 U.S.C. 552a (c)(3), (d), (e)(1), e(4)(G), (H) and (I), and (f).

EFFECTIVE DATE: April 7, 1999.

FOR FURTHER INFORMATION CONTACT: Margaret Peppe, 202–647–6338.

SUPPLEMENTARY INFORMATION: A notice of proposed rulemaking was published in the **Federal Register** (64 FR 922, January 6, 1999) inviting interested persons to submit comments concerning the proposed regulations. Since no comments were received, the amendment to the Privacy Provisions of the Department of State's Access to Information regulations was formally adopted as published.

List of Subjects in 22 CFR Part 171:

Privacy.

PART 171—[AMENDED]

1. The authority citation for part 171 continues to read as follows:

Authority: The Freedom of Information Act, 5 U.S.C. 552; the Privacy Act, 5 U.S.C. 552a; the Administrative Procedures Act, 5 U.S.C. 551, *et seq.*; the Ethics in Government Act, 5 U.S.C. App. 201; Executive Order 12958, 60 FR 19825; and Executive Order 12600, 52 FR 23781.

§ 171.32 [Amended]

2. In § 171.32, paragraph (j)(2) will be amended by adding ''Records of the Office of White House Liaison, STATE–34,'' after ''Records of the Inspector General and Automated Individual Cross-Reference System, STATE–53.''

Dated: March 1, 1999.

Patrick F. Kennedy,

Assistant Secretary for the Bureau of Administration.

[FR Doc. 99–5622 Filed 3–5–99; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 13

[T.D. ATF–406a]

RIN 1512–AB34

Procedures for the issuance, Denial, and Revocation of Certificates of Label Approval, Certificates of Exemption From Label Approval, and Distinctive Liquor Bottle Approvals (93F–029P); Correction

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Department of the Treasury.

ACTION: Final rule; correction.

SUMMARY: This document corrects the regulatory text of a final rule published in the **Federal Register** of January 13, 1999, regarding issuance, denial, and revocation of certificates of label approval, certificates of exemption from label approval, and distinctive liquor bottle approvals.

DATES: Effective March 15, 1999.

FOR FURTHER INFORMATION CONTACT: Edward A. Reisman, Product Compliance Branch, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue, NW, Washington, DC 20226, Telephone (202) 927–8140.

SUPPLEMENTARY INFORMATION: The Bureau of Alcohol, Tobacco and Firearms published a document in the **Federal Register** of January 13, 1999, (64 FR 2122). Several words were omitted from the text of 27 CFR 13.27. This document corrects this error.

In rule FR Doc. 99–624, published on January 13, 1999, make the following correction:

§ 13.27 [Corrected]

On page 2131, in the center column, correct the first full sentence of § 13.27(a) to read: ''The decision of the Chief, Product Compliance Branch, may be appealed in writing to the Chief,