

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.

216.23 [Reserved]

216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

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#### § 216.24 Drug products withdrawn or removed from the market for reasons of safety or effectiveness.

The following drug products were withdrawn or removed from the market because such drug products or components of such drug products were found to be unsafe or not effective.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.

*Dipyrrone*: All drug products containing dipyrrone.

*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 dermatologic 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.