DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98C–0041]

Ethicon, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ethicon, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of [phthalocyaninato(2-)] copper in coloring nonabsorbable sutures for general and opthalmic surgery made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).

DATES: Written comments on the petitioner's environmental assessment by March 4, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 721(d)(1) (21 U.S.C. 379e(d)(1)), notice is given that a color additive petition (CAP 8C0253) has been filed by Ethicon, Inc., P.O. Box 151, Somerville, NJ 08876–0151. The petition proposes to amend the color additive regulations in § 74.3045 *[Phthalocyaninato(2-)] copper* (21 CFR 74.3045) to provide for the safe use of [phthalocyaninato(2-)] copper in coloring nonabsorbable sutures for general and opthalmic surgery made from a blend of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before March 4, 1998, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: January 15, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–2497 Filed 1–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0009]

Medical Devices; Exemptions From Premarket Notification and Reserved Devices; Class I

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of class I devices, subject to certain limitations, that will be exempt from premarket notification requirements on February 19, 1998. FDA is also publishing a list of those class I devices that FDA believes will remain subject to premarket notification requirements because they meet the new statutory criteria for premarket notification requirements. These lists do not include class I devices that have been previously exempted by regulation from the premarket notification requirements. FDA is taking this action in order to meet a requirement of the Food and Drug Administration Modernization Act of 1997 (the FDAMA). The agency requests comments on whether the list of class I devices that will remain subject to the premarket notification requirements should be modified.

DATES: This notice is effective February 19, 1998. Submit written comments by May 4, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the act (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, class II, or class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), as amended by the Safe Medical Devices Act of 1990 (Pub. L. 101–629), devices are to be classified into class I (general controls) if there is information showing that the general controls of the act are sufficient to ensure safety and effectiveness; into class II (special controls), if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance; and into class III (premarket approval), if there is insufficient information to support classifying a device into class I or class II and the device is a life-sustaining or life-supporting device, or is for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury. Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified through the premarket notification process under section

510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, 21 CFR part 807, require persons who intend to market a new device to submit a premarket notification report containing information that allows FDA to determine whether the new device is substantially equivalent within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval. Unless exempted from premarket notification requirements, persons may not market a new device under section 510(k) of the act, unless they receive a substantial equivalence order from FDA or an order reclassifying the device into class I or class II, section 513(i) of the act. On November 21, 1997, the President signed into law the FDAMA (Pub. L. 105–115). Section 206 of the FDAMA, in part, added a new section 510(l) to the act. Under section 501 of the FDAMA, new section 510(l) of the act becomes 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 ''reserved criteria''). Based on these reserved criteria, FDA has evaluated all class I devices to determine which device types should be subject to premarket notification requirements.

In developing the list of reserved devices, the agency considered its experience in reviewing premarket notifications for these device types, focusing on the risk inherent with the device and/or the disease being treated or diagnosed, e.g., devices with rapidly evolving technology or expansions of intended uses. The agency considered the history of adverse event reports under the medical device reporting program for these devices, as well as their history of product recalls. Given the inherent risks with the devices listed and/or the disease or condition being treated or diagnosed, FDA believes that the devices listed as reserved are intended for a use that is of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury. In this notice, FDA is publishing two lists of devices: (1) A list of the class I devices that FDA believes will be exempt from the premarket notification requirements on February 19, 1998, under section 510(l) of the act, subject to certain limitations from the premarket notification requirements described herein; and (2) a list of the devices that FDA believes fit the reserved criteria under section 510(l) of the act and, therefore, will continue to be subject to premarket notification requirements. These lists do not include class I devices that have been previously exempted by regulation from the premarket notification requirements. FDA believes that class I devices that have previously been exempted generally do not fall within the reserved criteria under section 510(l) of the act. When FDA issues a proposed rule to amend the regulations to codify class I devices that remain subject to the premarket notification requirements, FDA, in limited cases, may propose to revoke the exemption from the premarket notification requirements based on the reserved criteria of section 510(l) of the act.

II. Limitations on Exemptions

As stated previously, FDA believes that the generic types of class I devices listed herein, in addition to a vast majority of class I devices previously exempted, should be exempt from the premarket notification requirements under section 510(l) of the act. FDA further believes, however, that these generic device categories should be exempt only to the extent that they have existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type or, in the case of in vitro diagnostic devices, for which a misdiagnosis as a result of using the device, would not be associated with high morbidity or mortality. FDA believes that certain changes to devices within a generic type that is generally exempt may make the device intended for a use that is of substantial importance in preventing impairment of human health or may make the device present a potential unreasonable risk of illness or injury. Accordingly, devices changed in this manner would fall within the reserved criteria under section 510(l) of the act and would require premarket notification.

FDA believes that devices that have different intended uses than legally marketed devices in that generic type present a potential unreasonable risk of illness or injury because their safety and effectiveness characteristics are unknown. Moreover, FDA believes that in vitro diagnostic devices that are intended for a use, for which a misdiagnosis as a result of using the device, could result in high morbidity or mortality, either are intended for a use that is of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury.

Accordingly, because FDA believes that devices incorporating the characteristics described above fit within the reserved criteria under section 510(l) of the act, FDA considers any class I device to be subject to premarket notification requirements if the device: (1) Has an intended use that is different from the intended use of a legally marketed device in that generic type; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or (2) operates using a different fundamental scientific technology than that used by a legally marketed device in that generic type, e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization or amplification technology rather than culture or immunoassay technology; or (3) is a in-vitro device that is intended: (a) For use in the diagnosis, monitoring or screening of neoplastic diseases with the exception of immunohistochemical devices; (b) for use in screening or diagnosis of familial and acquired genetic disorders, including inborn errors of metabolism; (c) for measuring an analyte that serves as a surrogate marker for screening, diagnosis, or monitoring life threatening diseases such as acquired immune deficiency syndrome (AIDS), chronic or active hepatitis, tuberculosis, or myocardial infarction or to monitor therapy; (d) to assess the risk of cardiovascular diseases; (e) for use in diabetes management; (f) to identify or infer the identity of a microorganism directly from clinical material; (g) for detection of antibodies to microorganisms other than immunoglobulin G (IgG) and IgG assays when the results are not qualitative, or are used to determine immunity, or the assay is intended for use in matrices other than serum or plasma; uses noninvasive testing; and (h) for near patient testing (point of care).

Class I devices incorporating such changes or modifications are not exempt from premarket notification because FDA believes they meet the reserved criteria described above, under 510(l).

In addition to the general limitation on exemptions that FDA considers applicable to all class I devices that is described above, FDA also considers certain devices within a generic class to remain subject to the premarket notification requirements because they

either are intended for a use that is of substantial importance in preventing impairment of human health or they present a potential unreasonable risk of illness or injury. For example, FDA, elsewhere in this document, states that it considers liquid bandages generally to be exempt from the premarket notification requirements, but considers a subcategory of those devices, those intended for treatment of burns and other open wounds, to remain subject to the premarket notification requirements. FDA believes that liquid bandages intended for burns and other open wounds should remain subject to this requirement because they are of substantial importance in preventing impairment of human health by helping to prevent infections.

FDA advises additionally that an exemption from the requirement of premarket notification does not mean that the device is exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation.

III. Lists of Devices

The following devices are devices that FDA believes meet the reserved criteria in section 206 of the FDAMA and, therefore, would remain subject to premarket notification under new section 510(l) added to the act:

TABLE 1.—RESERVED CLASS I DEVICES

21 CFR Section	Name of Device
862.1065	Ammonia test system
862.1113	Bilirubin (total and unbound) in the neonate test system
862.1410	Iron (non-heme) test system
862.1415	Iron-binding capacity test system
862.1495	Magnesium test system
862.1580	Phosphorous (inorganic) test system
862.1660	Quality control material (assayed and unassayed)[1]
862.1680	Testosterone test system
862.1775	Uric acid test system
862.3110	Antimony test system
862.3120	Arsenic test system
862.3220	Carbon monoxide test system
862.3240	Cholinesterase test system
862.3600	Mercury test system
864.7040	Adenosine triphosphate release assay
864.8950	Russell viper venom reagent
864.9050	Blood bank supplies
864.9125	Vacuum-assisted blood collection system
864.9195	Blood mixing devices and blood weighing devices[2]
866.2390	Transport culture medium
866.2560	Microbial growth monitor[3]
866.2850	Automated zone reader
866.2900	Microbiological specimen collection and transport device
866.3110	Campylobacter fetus serological reagents
866.3120	Chlamydia serological reagents
866.3235	Epstein-Barr virus serological reagents
866.3370	Mycobacterium tuberculosis immunofluorescent reagents
866.3870	Trypanosoma spp. serological reagents
872.4200	Dental handpiece and accessories
872.6250	Dental chair and accessories[4]
872.6640	Dental operative unit and accessories[5]
872.6710	Boiling water sterilizer
876.5160	Urological clamps for males[6]
878.4460	Surgeon's glove
880.5090	Liquid bandage[7]
880.5680	Pediatric position holder
880.6250	Patient examination glove
880.6375	Patient lubricant
880.6760	Protective restraint
882.1030	Ataxiagraph
882.1420	Electroencephalogram (EEG) signal spectrum analyzer
882.4060	Ventricular cannula[8]
882.4545	Shunt system implantation instrument[9]
884.2980(a)	Telethermographic system[10]
884.2982(a)	Liquid crystal thermographic system[11]
886.4070	Powered corneal burr[12]
886.4300	Intraocular lens guide[13]
886.4370	Keratome
888.1500	Goniometer
890.3850	Mechanical wheelchair
890.5710	Hot or cold disposable packs[14]
892.1100	Scintillation (gamma) camera
892.1110	Positron camera

[1] Meets reserved criteria when assayed and unassayed when used for donor screening.
[2] Meets reserved criteria when automated.
[3] Meets reserved criteria when automated blood culturing systems.
[4] Meets reserved criteria when dental chair with the operative unit.
[5] Meets reserved criteria when it is not the accessory tray to the unit.

[6] Meets reserved criteria when devices are for internal use or are used for females.
[7] Meets reserved criteria for uses other than as a skin protectant.
[8] Meets reserved criteria if not made of surgical grade stainless steel.
[9] Meets reserved criteria if not made of surgical stainless steel.
[10] Meets reserved criteria if an adjunct use system.
[11] Meets reserved criteria if nonelectrically powered and AC-powered adjunctive system.
[12] Meets reserved criteria if for use other than for removing rust rings.
[13] Meets reserved criteria if used as folders and injectors for soft or foldable IOL's.
[14] Meets reserved criteria if indicated for use on infants.

The following devices are devices that FDA believes do not meet the reserved criteria under section 206 of the FDAMA and, therefore, will be exempt from premarket notification as of February 19, 1998, under new section 510(l) added to the act:

TABLE 2.—EXEMPTED CLASS I DEVICES

21 CFR Section	Name of Device
862.1030	Alanine amino transferase (ALT/SGPT) test system
862.1040	Aldolase test system
862.1060	Delta-aminolevulinic acid test system
862.1075	Androstenedione test system
862.1080	Androsterone test system
862.1095	Ascorbic acid test system
862.1115	Urinary bilirubin and its conjugates (nonquantitative) test system
862.1130	Blood volume test system
862.1135	C-peptides of proinsulin test system
862.1165	Catecholamines (total) test system
862.1175	Cholesterol (total) test system
862.1180	Chymotrypsin test system
862.1185	Compound S (11-deoxycortisol) test system
862.1195	Corticoids test system
862.1200	Corticosterone test system
862.1240	Cystine test system
862.1245	Dehydroepiandrosterone (free and sulfate) test system
862.1250	Desoxycorticosterone test system
862.1260	Estradiol test system
862.1265	Estriol test system
862.1270	Estrogen (total, in pregnancy) test system
862.1275	Estrogens (total, nonpregnancy) test system
862.1280	Estrone test system
862.1285	Etiocholanolone test system
862.1300	Follicle-stimulating hormone test system
862.1310	Galactose test system
862.1325	Gastrin test system
862.1330	Globulin test system
862.1335	Glucagon test system
862.1360	Gamma-glutamyl transpeptidase and isoenzymes test system
862.1370	Human growth hormone test system
862.1375	Histidine test system
862.1385	17-Hydroxycorticosteroids (17-ketogenic steroids) test system
862.1390	5-Hydroxyindole acetic acid/serotonin test system
862.1395	17-Hydroxyprogesterone test system
862.1400	Hydroxyproline test system
862.1405	Immunoreactive insulin test system
862.1430	17-Ketosteroids test system
862.1435	Ketones (nonquantitative) test system
862.1450	Lactic acid test system
862.1460	Leucine aminopeptidase test system
862.1465	Lipase test system
862.1475	Lipoprotein test system
862.1485	Luteinizing hormone test system
862.1500	Malic dehydrogenase test system
862.1505	Mucopolysaccharides (nonquantitative) test sytem
862.1510	Nitrite (nonquantitative) test system
862.1520	5′-Nucleotidase test system
862.1530	Plasma oncometry test system
862.1535	Ornithine carbamyl transferase test system
862.1540	Osmolality test system
862.1542	Oxalate test system
862.1550	Urinary pH (nonquantitative) test system
862.1560	Urinary phenylketones (nonquantitative) test system
862.1570	Phosphohexose isomerase test system
862.1590	Porphobilinogen test system
862.1595	Porphyrins test system
862.1605	Pregnanediol test system

TABLE 2.—EXEMPTED CLASS I DEVICES—Continued

21 CFR Section	Name of Device
862.1610	Prenanetriol test system
862.1615	Pregnenolone test system
862.1620	Progesterone test system
862.1625	Prolactin (lactogen) test system
862.1630	Protein (fractionation) test system
862.1645	Urinary protein or albumin (nonquantitative) test system
862.1650	Pyruvate kinase test system
862.1655	Pyruvic acid test system
862.1660	Quality control material (assayed and unassayed)[1]
862.1705	Triglyceride test system
862.1725	Trypsin test system
862.1730	Free tyrosine test system
862.1780	Urinary calculi (stones) test system
862.1785	Urinary urobilinogen (nonquantitative) test system
862.1790	Uroporphyrin test system
862.1795	Vanilmandelic acid test system
862.1805	Vitamin A test system
862.1820	Xylose test system
862.2140	Centrifugal chemistry analyzer for clinical use
862.2150	Continuous flow sequential multiple chemistry analyzer for clinical use
862.2160	Discrete photometric chemistry analyzer for clinical use
862.2170	Micro chemistry analyzer for clinical use
862.2250	Gas liquid chromatography system for clinical use
862.2260	High pressure liquid chromatography system for clinical use
862.2270	Thin-layer chromatography system for clinical use
862.2300	Colorimeter photometer, or spectrophotometer for clinical use
862.2400	Densitometer/scanner (integrating, reflectance, TLC, or radiochromatogram) for clinical use
862.2500	Enzyme analyzer for clinical use
862.2540	Flame emission photometer for clinical use
862.2560	Fluorometer for clinical use
862.2680	Microtitrator for clinical use
862.2700	Nephelometer for clinical use
862.2730	Osmometer for clinical use
862.2750	Pipetting and diluting system for clinical use
862.2850	Atomic absorption spectrophotometer for clinical use
862.2860	Mass spectrometer for clinical use
862.2900	Automated urinalysis system
862.3280	Clinical toxicology control material
864.2280	Cultured animal and human cells
864.5240	Automated blood cell diluting apparatus
864.9185	Blood grouping view box
864.9195	Blood mixing devices and blood weighing devices[2]
864.9225	Cell-freezing apparatus and reagents for in vitro diagnostic use
864.9275	Blood bank centrifuge for in vitro diagnostic use
864.9320	Copper sulphate solution for specific gravity determination
864.9750	Heat-sealing device
866.2660	Microorganism differentiation and identification device
866.3040	*Aspergillus* spp. serological reagents
866.3140	*Corynebacterium* spp. serological reagents
866.3145	Coxsackievirus serological reagents
866.3200	*Echinococcus* spp. serological reagents
866.3240	Equine encephalomyelitis virus serological reagents
866.3355	*Listeria* spp. serological reagents
866.3360	Lymphocytic choriomeningitis virus serological reagents
866.3375	*Mycoplasma* spp. serological reagents
866.3380	Mumps virus serological reagents
866.3405	Poliovirus serological reagents
866.3480	Respiratory syncytial virus serological reagents
866.3500	Rickettsia serological reagents
866.3600	*Schistosoma* spp. serological reagents
866.3680	*Sporothrix schenckii* serological reagents
866.3740	*Streptococcus* spp. serological reagents
866.3850	*Trichinella spiralis* serological reagents
866.5060	Prealbumin immunological test system
866.5065	Human allotypic marker immunological test system
866.5160	*Beta-globulin* immunological test system
866.5200	Carbonic anhydrase B and C immunological test system
866.5330	Factor XIII, A, S, immunological test system[3]
866.5400	*Alpha*-globulin immunological test system
866.5420	*Alpha*-I-glycoproteins immunological test system
866.5425	*Alpha*-2-glycoproteins immunological test system
866.5430	*Beta*-2-glycoprotein I immunological test system

TABLE 2.—EXEMPTED CLASS I DEVICES—Continued

21 CFR Section	Name of Device
866.5440	*Beta*-2-glycoprotein III immunological test system
866.5560	Lactic dehydrogenase immunological test system
866.5570	Lactoferrin immunological test system
866.5590	Lipoprotein X immunological test system
866.5715	Plasminogen immunological test system
866.5735	Prothrombin immunological test system[4]
866.5765	Retinol-binding protein immunological test system
866.5890	Inter-*alpha* trypsin inhibitor immunological test system
868.1910	Esophageal stethoscope
868.5620	Breathing mouthpiece
868.5640	Medicinal nonventilatory nebulizer (atomizer)
868.5675	Rebreathing device
868.5700	Nonpowered oxygen tent
868.6810	Tracheobronchial suction catheter
872.3400(b)(1)	Karaya and sodium borate with or without acacia denture adhesive
874.1070	Short increment sensitivity index (SISI) adapter
874.1500	Gustometer
874.1800	Air or water caloric stimulator
874.1925	Toynbee diagnostic tube
874.3300(b)(1)	Hearing aid[5]
874.4100	Epistaxis balloon
874.5300	Ear, nose, and throat examination and treatment unit
874.5550	Powered nasal irrigator
874.5840	Antistammering device
876.5160	Urological clamps for males[6]
876.5210	Enema kit
876.5250(b)(2)	Urine collector and accessories
878.4040	Surgical apparel[7]
878.4200	Introduction/drainage catheter and accessories
878.4320	Removable skin clip
878.4680	Nonpowered, single patient, portable suction apparatus
878.4760	Removable skin staple
878.4820	Surgical instrument motors and accessories/attachments
878.4960	Operating tables and accessories and operating chair and accessories
880.5090	Liquid bandage[8]
880.5270	Neonatal eye pad
880.5420	Pressure infusor for an I.V. bag
882.4060	Ventricular cannula[9]
882.4545	Shunt system implantation instrument[10]
882.4650	Neurosurgical suture needle
882.4750	Skull punch[11]
884.1040	Viscometer for cervical mucus
886.1350	Keratoscope[12]
886.1780	Retinoscope[13]
886.1940	Tonometer sterilizer
886.4070	Powered corneal burr[14]
886.4300	Intraocular lens guide[15]
886.5850	Sunglasses (nonprescription)
890.5180	Manual patient rotation bed
890.5710	Hot or cold disposable pack[16]
892.1300	Nuclear rectilinear scanner
892.1320	Nuclear uptake probe
892.1330	Nuclear whole body scanner
892.1410	Nuclear electrocardiograph synchronizer
892.1890	Radiographic film illuminator
892.1910	Radiographic grid
892.1960	Radiographic intensifying screen
892.1970	Radiographic ECG/respirator, synchronizer
892.5650	Manual radionuclide applicator system

[1] Exemption is limited to unassayed material, except when used in conjunction with donor screening tests.
[2] Exemption is limited to manual devices.
[3] This exemption should not be confused with § 864.7290.
[4] This exemption should not be confused with §§ 864.5425 or 864.7750.
[5] Exemption is limited to air-conduction hearing aids.
[6] Exemption does not include devices for internal use or devices used for females.
[7] Exemption is limited to class I category other than surgical gowns and surgical masks.
[8] Exemption is limited to uses as a skin protectant.
[9] Exemption is limited to surgical grade stainless steel.
[10] Exemption is limited to devices made of surgical grade stainless steel.
[11] Exemption should not be confused with § 882.4305.
[12] Exemption is extended to those with software.
[13] Exemption is limited to class I battery-powered devices.
[14] Exemption is limited to rust ring removal.

[15] Exemption does not apply if used as folders and injectors for soft or foldable IOL's.
[16] Exemption does not apply when indicated for infants.

IV. Comments

Interested persons may, on or before May 4, 1998, submit to the Dockets Management Branch (address above) written comments regarding the notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 23, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–2498 Filed 1–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 12, 1998, 8:30 a.m. to 5 p.m.

Location: Parklawn Bldg., conference rooms G and H, 5600 Fishers Lane, Rockville, MD.

Contact Person: Mary J. Cornelius, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12523. Please call the Information Line for up-to-date information on this meeting.

Procedure: On February 12, 1998, from 9:30 a.m. to 10:30 a.m., the meeting will be open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by February 6, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before February 6, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On February 12, 1998, from 10:30 a.m. to 5 p.m., FDA staff will present to the committee confidential information regarding present and future device issues. The committee will also hear and review trade secret and/or confidential commercial information on a product development protocol. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4).

FDA regrets that it was unable to publish this notice 15 days prior to the February 12, 1998, Gastroenterology and Urology Devices Panel of the Medical Devices meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Gastroenterology and Urology Devices Panel of the Medical Devices were available at this time, the Commissioner concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 26, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–2409 Filed 1–30–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on February 12, 1998, 9:30 a.m. to 5:30 p.m., and February 13, 1998, 9:30 a.m. to 6 p.m.

Location: Corporate Bldg., conference room 020B, 9200 Corporate Blvd., Rockville, MD.

Contact Person: Freddie M. Poole, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–2096, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12517. Please call the Information Line for up-to-date information on this meeting.

Agenda: On February 12, 1998, the committee will provide advice and recommendations to the agency on issues regarding tests for hepatitis viruses intended for detecting antigens or nucleic acids of hepatitis viruses B and C, or antibodies (total, IgG, or IgM) to antigens of hepatitis viruses A, B, and C. These assays may be indicated for the diagnosis of current (acute or chronic), recent, or past infection; management of current infection; determination of prior immunologic experience or pre- and post-vaccination antibody responses. These devices are not indicated for screening donors of blood or blood products, unless specifically indicated for such uses. The intent of the committee discussion is not to resolve issues related to the clinical practice or treatment of patients with viral hepatitis. Rather, the focus of discussion will be on appropriate clinical studies for establishing the safety and effectiveness of devices for these hepatitis viruses when used for the previously stated indications for use. On February 13, 1998, the committee will discuss a petition for reclassification of fully automated short-term incubation cycle antimicrobial susceptibility devices from class III to class II.

Procedure: On February 12, 1998, from 9:30 a.m. to 5:30 p.m., and on February 13, 1998, from 10 a.m. to 6