to comment to do so at the earliest possible time to permit the fullest consideration of their views.

The period for submission of comments will close on July 13, 2000. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the person submitting the comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form.

Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be made available for public inspection.

The public record concerning these regulations will be maintained in the Bureau of Export Administration Freedom of Information Records Inspection Facility, Room 6883, Department of Commerce, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in Part 4 of Title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at the facility may be obtained from the Bureau of Export Administration Freedom of Information Officer at the above address or by calling (202) 482–0500.

List of Subjects in 15 CFR Part 774

Exports, Foreign trade.

Accordingly, part 774 of the Export Administration Regulations (15 CFR parts 730 through 799) is amended as follows:

1. The authority citation for part 774 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 18 U.S.C. 2510 *et seq.*; 22 U.S.C. 287c; 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; Sec. 201, Pub. L. 104–58, 109 Stat. 557 (30 U.S.C. 185(s)); 30 U.S.C. 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 46 U.S.C. app. 466c; 50 U.S.C. app. 5; E.O. 12924, 59 FR 43437, 3 CFR, 1994 Comp., p. 917; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; Notice of August 10, 1999 (3 CFR, 1999 Comp. 302 (2000)).

PART 774—AMENDED

Supplement No. 1 to Part 774—Amended

2. In Supplement No. 1 to part 774 (the Commerce Control List), Category 3—Electronics, Export Control Classification Number (ECCN) 3A001 is amended by revising the License Exceptions section to read as follows:

3A001 Electronic components, as follows (see List of Items Controlled).

* * * * *

License Exceptions

LVS: N/A for MT
$1500: 3A001.c
$3000: 3A001.b.1, b.2, b.3, .d, .e and .f
$5000: 3A001.a, and .b.4 to b.7
GBS: Yes, except 3A001.a.1.a, b.1, b.3 to b.7, .c to .f
CIV: Yes, except 3A001.a.1, a.2, a.3.a (for processors with a CTP greater than 4500 Mtops), a.5, a.6, a.9, a.10, and a.12, .b, .c, .d, .e, and .f

* * * * *

3. In Supplement No. 1 to part 774 (the Commerce Control List), Category 4—Computers, Export Control Classification Number (ECCN) 4A003 is amended by revising the License Exceptions section to read as follows:

4A003 ''Digital computers'', ''electronic assemblies'', and related equipment therefor, and specially designed components therefor.

* * * * *

License Exceptions

LVS: $5000; N/A for MT and ''digital'' computers controlled by 4A003.b and having a CTP exceeding 10,000 MTOPS; or ''electronic assemblies'' controlled by 4A003.c and capable of enhancing performance by aggregation of ''computing elements'' so that the CTP of the aggregation exceeds 10,000 MTOPS.
GBS: Yes, for 4A003.d, .e, and .g and specially designed components therefor, exported separately or as part of a system.
CTP: Yes, for computers controlled by 4A003.a, .b and .c, to the exclusion of other technical parameters, with the exception of parameters specified as controlled for Missile Technology (MT) concerns and 4A003.e (equipment performing analog-to-digital or digital-to-analog conversions exceeding the limits of 3A001.a.5.a). See § 740.7 of the EAR.
CIV: Yes, for 4A003.d (having a 3–D vector rate less than or equal to 100 M vectors/sec), .e, and .g.

* * * * *

Dated: June 8, 2000.

R. Roger Majak,

Assistant Secretary for Export Administration.

[FR Doc. 00–14903 Filed 6–12–00; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 92F–0443]

Indirect Food Additives: Adhesives and Components of Coatings; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its food additives regulations to correct two typographical errors in the Chemical Abstracts Service (CAS) registry number. This document corrects those errors.

DATES: This rule is effective June 13, 2000.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3091.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 11, 2000 (65 FR 6889), the agency amended the food additive regulations to provide for the safe use of: (1) 1,2-dibromo-2,4-dicyanobutane, and (2) a mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one, optionally containing magnesium nitrate, as antimicrobial agents in emulsion-based silicone coating formulations. The CAS registry number for 2-methyl-4-isothiazol-3-one was incorrectly published. The agency is amending both 21 CFR 175.300 and 175.320 to correct those errors.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 175.300 [Amended]

2. Section 175.300 *Resinous and polymeric coatings* is amended in paragraph (b)(3)(xxxiii), under the entry ''5-Chloro-2-methyl * * *'', by removing ''(CAS Reg. No. 2628–20–4)'' and adding in its place ''(CAS Reg. No. 2682–20–4)''.

3. Section 175.320 is amended in the table in paragraph (b)(3) by revising the entry under item (iii) for ''5–Chloro-2-methyl-4-isothiazolin-3-one'' under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 175.320 Resinous and polymeric coatings for polyolefin films.

* * * * *

(b) * * *

(3) * * *

List of substances	Limitations
* * * * * * *	
(iii) Adjuvants (release agents, waxes, and dispersants):	
* * * * * * *	
5-Chloro-2-methyl-4-isothiazolin-3-one (CAS Reg. No. 26172–55–4) and 2-methyl-4-isothiazolin-3-one (CAS Reg. No. 2682–20–4) mixture, at a ratio of 3 parts to 1 part, respectively, manufactured from methyl-3-mercaptopropionate (CAS Reg. No. 2935–90–2) and optionally containing magnesium nitrate (CAS Reg. No. 10377–60–3) at a concentration equivalent to the isothiazolone active ingredients (weight/weight).	For use only as an antimicrobial agent in emulsion-based silicone coatings at a level not to exceed 50 milligrams per kilogram (based on isothiazolone active ingredient) in the coating formulation.
* * * * * * *	

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Dated: June 7, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–14905 Filed 6–12–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. 99N–2099]

General Hospital and Personal Use Devices; Classification of the Subcutaneous, Implanted, Intravascular Infusion Port and Catheter and the Percutaneous, Implanted, Long-term Intravascular Catheter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the subcutaneous, implanted, intravascular (IV) infusion port and catheter, and the percutaneous, implanted, long-term IV catheter intended for repeated vascular access into class II (special controls). This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: This rule is effective July 13, 2000.

FOR FURTHER INFORMATION CONTACT: M. Patricia Cricenti, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1287.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (the SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act