18. Romsos, D. R., P. S. Belo, and G. A. Leveille, ''Butanediol and Lipid Metabolism,'' *Federation Proceedings*, 34:2186–2190, 1975.

19. Tate, R. L., M. A. Mehlman, and R. B. Tobin, ''The Metabolism of 1,3-Butanediol'' (undated).

20. Tate, R. L., M. A. Mehlman, and R. B. Tobin, ''Metabolic Fate of 1,3-Butanediol in the Rat: Conversion to β-Hydroxybutyrate,'' *Journal of Nutrition*, 101:1719–1726, 1971.

21. Tobin, R. B., M. A. Mehlman, C. Kies, H. M. Fox, and J. S. Soeldner, ''Nutritional and Metabolic Studies in Humans With 1,3-Butanediol,'' *Federation Proceedings*, 34:2171–2176, 1975.

22. ''Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food'' in ''Redbook,'' Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1982. Available through National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, order number PB–83–170696. Revised draft is available from the Office of Premarket Approval (HFS–206), 200 C St. SW., Washington, DC 20204–0001.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. New § 172.712 is added to subpart H to read as follows:

§ 172.712 1,3-Butylene glycol.

The food additive 1,3-butylene glycol (CAS Reg. No. 107–88–0) may be safely used in food in accordance with the following prescribed conditions:

(a) It is prepared by the aldol condensation of acetaldehyde followed by catalytic hydrogenation.

(b) The food additive shall conform to the identity and specifications listed in the monograph entitled ''1,3-Butylene Glycol'' in the Food Chemicals Codex, 4th ed. (1996), p. 52, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Office of Premarket Approval, Center for Food Safety and Applied Nutrition, 200 C St. SW., Washington, DC 20204–0001, or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) It is used in the manufacture of sausage casings as a formulation aid as defined in § 170.3(o)(14) of this chapter and as a processing aid as defined in § 170.3(o)(24) of this chapter.

Dated: April 14, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–12461 Filed 5–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

Export Requirements for Medical Devices; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for exporting devices for investigational use to correct the statutory reference. This action is being taken to reflect changes in the Federal Food, Drug, and Cosmetic Act (the act), and to ensure the accuracy and consistency of the regulations.

EFFECTIVE DATE: May 13, 1997.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20850, 301–827–3380.

SUPPLEMENTARY INFORMATION: At present, two statutory provisions in the act govern the export of devices that are not approved for marketing in the United States. The first provision, at section 801(e)(2) of the act (21 U.S.C. 381(e)(2)), became law as part of the Medical Device Amendments Act of 1976 (Pub. L. 94–295) and required FDA's approval of certain exports of unapproved devices.

The second provision, now codified as section 802 of the act (21 U.S.C. 382), was the result of the FDA Export Reform and Enhancement Act of 1996 (Pub. L. 104–134, and amended by Pub. L. 104–180) (the Export Act of 1996). The Export Act of 1996 amended, among other things, sections 801 and 802 of the act. The Export Act of 1996 amended section 801(e)(2) of the act to state, in part, that export of an unapproved device may occur only if the agency determines that exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export or ''the device is eligible for export under section 802'' of the act. Section 802 of the act, as amended, authorizes exports of unapproved drugs and devices if certain conditions or requirements are met. Under section 802(b)(1) of the act, an unapproved device may be exported to any country if the device complies with the laws of that country and has valid marketing authorization in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, or in any country in the EU or the EEA (often referred to as the ''listed countries''). At present, the EU countries are Austria, Belgium, Denmark, Germany, Greece, Finland, France, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The EEA countries are the EU countries, plus Iceland, Liechtenstein, and Norway. As new countries join the EU or the EEA, they will automatically be treated as listed countries without any need for FDA action. Additionally, the Secretary of Health and Human Services may designate additional countries to be added to the list if certain requirements are met.

Other provisions of the Export Act of 1996 permit devices to be exported, without prior FDA approval, for investigational use in the listed countries and to be exported in anticipation of market authorization in the listed countries (section 802(c) and (d) of the act). Prior FDA approval is required for devices intended for use in the treatment of a tropical disease or a disease that is not of significant prevalence in the United States (section 802(e) of the act).

All devices exported under section 802 of the act are subject to certain requirements, under section 802(f) of the act. For example, the device must be manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements or meet international standards as certified by an international standards organization recognized by the agency; must not be adulterated under section 501(a)(1), (2)(A), or (3) (21 U.S.C. 351(a)(1), (2)(A), or (3)) or section 501(c) of the act; and must comply with sections 801(e)(1)(A) through (D) of the act (which require the

device to accord to the foreign purchaser's specifications, not be in conflict with the laws of the foreign country to which the device is being exported, be labeled on the outside of the shipping package that the device is intended for export, and not be sold or offered for sale in domestic commerce).

The only regulation pertaining to exports of unapproved devices for investigational use is at 21 CFR 812.18(b). The provision, which was originally written decades ago, simply stated that, ''A person exporting an investigational device subject to this part shall obtain FDA's prior approval as required by section 801(d) of the act.'' However, since the provision was written, Congress has amended the act twice; under the Drug Export Amendments Act of 1986, section 801(d) of the act was renumbered to become section 801(e) of the act, and the Export Act of 1996 established section 802 of the act as an alternative export mechanism for unapproved devices for investigational use. Consequently, FDA is amending § 812.18(b) to state that, ''A person exporting an investigational device subject to this part shall obtain FDA's prior approval as required by section 801(e) of the act or shall comply with the applicable export requirements in section 802 of the act.'' This amendment reflects the correct paragraph in section 801 of the act that applies to investigational device exports as well as the export mechanisms in section 802 of the act.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)). Notice and public procedure are unnecessary because FDA is merely correcting a statutory reference.

List of Subjects in 21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 812 is amended as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

1. The authority citation for 21 CFR part 812 is revised to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801, 802, 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381, 382, 383); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

2. Section 812.18 is amended by revising paragraph (b) to read as follows:

§ 812.18 Import and export requirements.

* * * * *

(b) *Exports.* A person exporting an investigational device subject to this part shall obtain FDA's prior approval, as required by section 801(e) of the act or comply with section 802 of the act.

Dated: May 6, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12524 Filed 5–12–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CCGD11–97–003]

RIN 2115–AE46

Special Local Regulations: California Cup

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements 33 CFR 100.1101, ''Southern California Marine Events,'' for the 1997 California Cup Race. This event consists of a sailboat race with approximately 250 participants. These regulations will be effective in the portion of Santa Monica Bay off Santa Monica, California described in Table 1 to 33 CFR 100.1101. Implementation of section 33 CFR 11.1101 is necessary to control vessel traffic in the regulated area during the race to ensure the safety of participants and spectators.

DATES: The regulations in 33 CFR 100.1101 are effective from 2 p.m. until 5 p.m. on 23 May 1997, and from 11 a.m. until 5 p.m. on 24 and 25 May 1997, unless cancelled earlier by the Patrol Commander.

FOR FURTHER INFORMATION CONTACT: QMC D.K. LARSON, U.S. Coast Guard Marine Safety Office/Group Los Angeles/Long Beach, 165 N. Pico Avenue, Long Beach, California 90802; Tel: (310) 980–4442.

SUPPLEMENTARY INFORMATION: The California Cup is scheduled to occur on 23, 24 and 25 May 1997. These Special Local Regulations permit Coast Guard control of vessel traffic in order to ensure the safety of spectator and participant vessels. In accordance with the regulations in 33 CFR 100.1101, persons and vessels shall not anchor in or loiter in the regulated area, or impede the transit of participant or official patrol vessels, unless authorized by the Coast Guard Patrol Commander.

Dated: May 5, 1997.

R.T. Rufe, Jr.,

Vice Admiral, U.S. Coast Guard Commander, Eleventh Coast Guard District, Alameda, California.

[FR Doc. 97–12485 Filed 5–12–97; 8:45 am]

BILLING CODE 4910–14–M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

33 CFR Part 325

Processing of Department of the Army Permits

AGENCY: Army Corps of Engineers, DoD.

ACTION: Final rule.

SUMMARY: The Corps is making several minor editorial changes to its permit regulations to reflect a change in the title of a Division Office in the National Ocean Service (NOS), National Oceanic and Atmospheric Administration and the Agency's change of address. This amendment is necessary because Corps regulations require notification of the NOS by Corps Districts and permittees under certain circumstances.

EFFECTIVE DATE: May 13, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph Eppard, HQUSACE, Regulatory Branch, CECW–OR at (202) 761–1783.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in sections 9 and 10 of the Rivers and Harbors Act of 1899 and section 404 of the Clean Water Act, the Corps issued regulations for the Regulatory Program in 33 CFR 320–330. In § 325.2(a)(9) (i) and (iii) and § 325.3(d)(2)(ii), and Appendix A–Permit Form and Special Conditions, a reference is made to the Charting and Geodetic Services, N/CG222, National Ocean Service, NOAA, Rockville, Maryland 20852. The correct identity and address for that Agency has changed and is now the National Ocean Service, Office of Coast Survey, N/CS261, 1315 East West Highway, Silver Spring, Maryland 20910–3282.

No other changes are being made to the permit regulations.

Procedural Requirements:

a. Review Under Executive Order 12866

The amendments contained in this rule are editorial and only reflect