December 8, 1994; certificated in any category.

**Note 1:** This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been otherwise modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

*Compliance:* Required as indicated, unless accomplished previously.

To prevent wires in the area above the main passenger door from becoming worn or breaking, which could lead to the failure of several systems, such as the fuel shutoff valves that allow the flight crew to stop the flow of fuel in the event of an engine fire, accomplish the following:

(a) Within 12 months after the effective date of this AD, conduct a one-time inspection to detect worn or broken wires in the wire bundles installed above the main passenger door, in accordance with Boeing Service Bulletin 767–33–0052, Revision 1, dated December 8, 1994. Prior to further flight, repair any worn or broken wires and relocate the wire bundles inboard of this door, in accordance with the service bulletin. Thereafter, no further action is required by this AD.

**Note 2:** Inspection; repair, if necessary; and relocation of the wire bundles accomplished prior to the effective date of this AD in accordance with Boeing Service Bulletin 767–33–0052, dated April 2, 1992, is considered acceptable for compliance with the requirements of paragraph (a) of this AD.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

**Note 3:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on May 30, 1997.

**Darrell M. Pederson,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 97–14771 Filed 6–5–97; 8:45 am]

BILLING CODE 4910–13–U

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Part 812

**[Docket No. 95N–0342]**

## Export Requirements for Medical Devices; Withdrawal of Proposed Rule

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing a proposed rule that appeared in the **Federal Register** of November 27, 1995 (60 FR 58308). The proposed rule would have amended FDA's regulations for exporting devices for investigational use. FDA is withdrawing the proposed rule because recent statutory changes have made the rulemaking unnecessary.

**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 Federal Food, Drug, and Cosmetic Act (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 approval of certain exports of unapproved devices. The second provision, 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) (Export Act of 1996).

Before the latter provision became law, FDA had undertaken a program to streamline the requirements for the exportation of unapproved devices under section 801(e) of the act. FDA issued a proposed rule to simplify the agency's export approval process for certain unapproved devices (60 FR 58308). The proposed rule was intended, in part, to respond to concerns in the device industry that the statutory requirement of FDA approval of device exports may undermine a firm's ability to compete in international markets and may represent an unnecessary regulatory barrier. (It should be emphasized, however, that FDA's approval times for device export applications have decreased significantly, from an average of 91 days per request in 1992, to 10 days in 1995, and further decreased to 8 days in fiscal year 1996.) The proposed rule was also intended to implement part of the President's and Vice-President's ''National Performance Review'' pertaining to the exportation of unapproved devices (as announced in an April, 1995 report entitled, ''Reinventing Drug and Device Regulations''). Under the National Performance Review initiative, the agency would permit the export of unapproved devices to certain advanced industrialized countries without prior FDA review and approval, provided that the device complied with the importing country's laws. The report also stated that the Administration would seek the necessary legislative changes and would consult Congress on the appropriate list of advanced industrialized countries.

The report also stated that FDA would initiate administrative changes to permit exports to countries that are not on the list of advanced industrialized countries ''if the exporter has an Investigational Device Exemption (IDE) permitting testing on humans in the United States, the importing country has given FDA a letter providing blanket approval for IDE-type devices, and the device is in compliance with the importing country's laws.'' Consequently, FDA proposed to amend 21 CFR 812.18 to state that a person who wishes to export an investigational device subject to part 812 (21 CFR part 812) (investigational devices) must comply with the requirements at section 801(e)(1) of the act, but that, for purposes of section 801(e)(2) of the act, prior FDA approval would be unnecessary if the investigational device to be exported is the subject of an approved IDE (including nonsignificant risk devices which, under FDA regulations, are considered to have an approved IDE) and ''will be marketed or used in clinical trials in the foreign country for the same intended use as that in the approved IDE and is to be exported to a country that has expressed its approval of the importation of investigational devices'' that are the subject of an approved IDE. The proposed rule also stated that, if the device is the subject of an approved IDE and has received a ''CE'' mark from the European Union (EU), the device may be exported to any country in the European Economic Area (EEA).

The proposed rule also would have FDA make available a list of countries that have approved the importation of investigational devices that are the subjects of approved IDE's. Additionally, the proposal would require prior FDA approval to export an

investigational device if FDA withdrew approval of the IDE or the sponsor terminated any or all parts of investigations because unanticipated adverse device effects present an unreasonable risk to subjects.

In the preamble to the proposed rule, FDA also stated that it would amend the proposed rule to reflect any legislative changes (60 FR 58308 at 58309).

The agency received 7 comments on the proposed rule. Most comments supported the rule, but recommended expanding the rule to explicitly mention certain devices (such as intraocular lenses and certain in vitro diagnostic devices), amending the rule so that a CE mark would permit exportation of the device to any country, or amending the rule to consider marketing authorization by developed countries as permitting exportation to any country. One comment questioned the likelihood that a country would agree to the importation of all devices having approved IDE's.

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 could occur only if the agency has determined 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.

Another provision of the Export Act of 1996 pertains specifically to drugs and devices exported for investigational use. Section 802(c) of the act states that a drug or device intended for investigational use in any country described in section 802(b)(1)(A)(i) or (b)(1)(A)(ii) of the act ''may be exported in accordance with the laws of that country and shall be exempt from regulation under section 505(i) or 520(g)'' of the act. Thus, under section 802(c) of the act, as amended, a device may be exported for investigational use to any of the listed countries without prior FDA approval and without compliance with the IDE regulations at part 812.

However, all devices exported under section 802 of the act are subject to certain requirements, under section 802(f) and (g) 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) or section 501(c) of the act; and must comply with section 801(e)(1)(A) through (e)(1)(D) of the act (which requires 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). Further, exporters must maintain records of products exported.

The Export Act of 1996 affected the proposed rule in several ways. First, it accomplished some changes to the proposed rule that the comments requested, particularly those comments that requested that FDA expand the proposed rule to cover other devices and other FDA-regulated products or requested FDA to permit exportation to any country if a device received marketing authorization in the EU or marketing authorization in a ''developed country.'' Second, the Export Act of 1996 also distinguished between exports under section 801(e) of the act and exports under section 802 of the act. For example, when FDA published the proposed rule on November 27, 1995, devices were subject only to the requirements in section 801(e) of the act. The Export Act of 1996 gave firms an option whether to export a device under section 801(e) of the act or under section 802 of the act, and assigned different requirements to exports under each section.

Finally, as stated earlier, section 802(b)(1)(A) of the act authorizes export of an unapproved device to any country if the device complies with the laws of the importing country and the device has a valid marketing approval in any of the countries identified in the act. Devices exported under section 802(b)(1)(A) of the act are neither required to obtain prior FDA approval (although they are subject to certain notification and recordkeeping requirements) nor are they required to have an IDE. In contrast, the proposed rule's reference to exports of investigational devices for marketing purposes would have been limited to devices exported under section 801(e)(2) of the act and presumed that the person exporting the device has an IDE or is considered to have an approved IDE.

Section 802(c) of the act, as revised by the Export Act of 1996, also had a significant impact on the proposed rule. Under section 802(c) of the act, devices exported for investigational use to any listed country are not subject to the IDE requirements and can be exported without prior FDA approval. In comparison, the proposed rule would have required the exported device to have an approved IDE or to be a nonsignificant risk device and be considered to have an approved IDE, and the streamlined requirements described in the proposal would have applied only to exports to countries that had notified FDA of their willingness to accept IDE devices.

Considering these changes in the export authority for devices and their effect on the proposed rule, FDA published a notice in the **Federal Register** on January 7, 1997 (62 FR 953) to reopen the comment period for the proposed rule and to solicit public comment on whether the proposed rule was still necessary. The agency received three comments in response to its notice, and all three comments agreed that the statutory changes eliminated the need for the proposed rule. FDA agrees with the comments, and, through this notice, is withdrawing the proposed rule that appeared in the **Federal Register** on November 27, 1995.

In the **Federal Register** of May 13, 1997 (62 FR 26228), the agency amended § 812.18 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 statutory references. At this time the agency believes that no further amendment to these regulations is necessary.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 301, 501,

502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801, 802, and 803) and under 21 CFR 5.10, the proposed rule published in the **Federal Register** of November 27, 1995 (60 FR 58308), is withdrawn.

Dated: May 29, 1997.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 97–14749 Filed 6–5–97; 8:45 am]

BILLING CODE 4160–01–F

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 9, 122, 123, 131, and 132

**[FRL–5836–4]**

### Final Water Quality Guidance for the Great Lakes System Draft Mercury Permitting Strategy

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability of document for public review and comment.

**SUMMARY:** EPA is making a draft of the Mercury Permitting Strategy (''Strategy'') available for public review and comment for a 60-day period. The purpose of the Strategy is to identify how the Final Water Quality Guidance for the Great Lakes System (''Guidance'') provides for implementation of mercury water quality standards though National Pollutant Discharge Elimination System (''NPDES'') permits for point sources, focusing on the flexibility States or Tribes have for adjusting point source controls to account for non-point sources of mercury. The draft Strategy also addresses several permit implementation issues related to mercury data.

**DATES:** Written comments on this draft Strategy will be accepted until August 5, 1997.

**ADDRESSES:** Comments on the draft Mercury Permitting Strategy should be addressed to Debora Clovis, U.S. EPA, Permits Division (4203), 401 M Street, S.W., Washington, D.C. 20460. EPA will also accept comments electronically. Comments should include the sender's name, address, and telephone number and be sent to the following E-Mail address: clovis.debora@epamail.epa.gov. Copies of the draft Mercury Permitting Strategy are available from the following EPA Regional Offices:

*Philip Sweeney*—Region 2, Water Management Division, 212–637–3873; fax: 212–637–3887;

*Chuck Sapp*—Region 3, Water Management Division, 215–566–5725; fax: 215–566–2301;

*Mary Jackson-Willis*—Region 5, Water Quality Branch, 312–886–3717; fax: 312–886–7804;

Copies may also be obtained by calling Mildred Thomas at (202) 260–6054.

EPA will place this notice and the draft Strategy on the Internet for public review and downloading at the following location: www.epa.gov/owm/wm030000.htm. Users with access to computer bulletin boards may view and download the draft Strategy on PIPES, the Point Source Information Provisions and Exchange System. The bulletin board service phone number is (703) 749–9216. [Modem settings should be set at 8-N–1/; terminal emulation should be ''ANSI'' or ''VT–100.]

**FOR FURTHER INFORMATION CONTACT:** Debora Clovis, Permits Division (4203), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460, (202) 260–9519.

**SUPPLEMENTARY INFORMATION:** On March 23, 1995, EPA published the Final Water Quality Guidance for the Great Lakes System (''Guidance'') (60 FR 15366). As required by Section 118(c)(2) of the Clean Water Act, the Guidance establishes minimum water quality criteria, methodologies, policies, and procedures for the Great Lakes System. States and Tribes in the Great Lakes Basin are required to adopt provisions into their water quality standards and National Permit Discharge Elimination System (NPDES) permit programs that are consistent with the Guidance within two years after publication of the Guidance (March 23, 1997). A major purpose of the Guidance is to establish consistent, enforceable, long-term protection for fish and shellfish in the Great Lakes and their tributaries, as well as for the people and wildlife who consume them.

In developing the Guidance, EPA recognized that control of mercury releases to the environment to achieve water quality standards could be a particularly difficult challenge. Mercury is persistent, ubiquitous, and harmful to human health and the environment at relatively low levels. Mercury finds its way to the water column from point and non-point sources. Non-point sources, particularly air deposition, are considered to be the most significant remaining contributors of mercury to the Great Lakes System. For these reasons, several stakeholders in the Great Lakes Basin advocated in their comments on the proposed Guidance that any additional controls on point source discharges of mercury effectively be suspended. In response, EPA stated that the Guidance contained appropriate flexibility to address the unique problems posed by mercury. It also committed to developing a mercury permitting strategy.

Today, EPA is making its draft Mercury Permitting Strategy (''Strategy'') available for public review and comment for a 60-day period. The purpose of the Strategy is to identify how the Guidance provides for implementation of mercury water quality standards though NPDES permits for point sources, focusing on the flexibility States or Tribes have for adjusting point source controls to account for non-point sources of mercury. The draft Strategy also addresses several permit implementation issues related to mercury data.

Dated: May 29, 1997.

**Robert Perciasepe,**

*Assistant Administrator, Office of Water.*

[FR Doc. 97–14858 Filed 6–5–97; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

**[AZ 69–0012; FRL–5836–9]**

### Approval and Promulgation of Implementation Plans; Arizona—Maricopa County PM–10 Nonattainment Area

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve in part and disapprove in part the final *Plan for Attainment of the 24-hour PM–10 Standard—Maricopa County PM–10 Nonattainment Area,* (May 1997) (plan or microscale plan) submitted by the Arizona Department of Environmental Quality on May 7, 1997. The microscale plan evaluates attainment of the 24-hour particulate matter (PM–10) national ambient air quality standard at four monitoring locations in the Maricopa County (Phoenix), Arizona, PM–10 nonattainment area. EPA is proposing to approve the attainment and reasonable further progress (RFP) demonstrations for two of these sites (Salt River and Maryvale) and disapprove them for two other sites (West Chandler and Gilbert). EPA is also proposing to approve the reasonably available control measure/best available control measure (RACM/BACM) demonstrations in the