

amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

#### PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

1. The authority citation for part 97 is revised to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120, 44701; and 14 CFR 11.49(b)(2).

2. Part 97 is amended to read as follows:

#### §§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLS/DME, MLS/RNAV/ § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

\* \* \* *Effective April 22, 1999*

Shelbyville, IN, Shelbyville Muni, VOR RWY 19, Orig  
Shelbyville, IN, Shelbyville Muni, VOR OR GPS RWY 18, Amdt 9, CANCELLED  
Burlington, NC, Burlington-Alamance Regional, NDB RWY 6, Orig  
Burlington, NC, Burlington-Alamance Regional, NDB RWY 6, Amdt 4, CANCELLED

\* \* \* *Effective May 20, 1999*

Anaktuvuk Pass, AK, Anaktuvuk Pass, NDB-B, Orig  
Anaktuvuk Pass, AK, Anaktuvuk Pass, GPS-A, Orig  
Nome, AK, Nome, MLS RWY 9, Orig, CANCELLED  
Port Heiden, AK, Port Heiden, VOR/DME RWY 13, Amdt 1  
Port Heiden, AK, Port Heiden, NDB RWY 5, Amdt 5  
Port Heiden, AK, Port Heiden, NDB/DME RWY 5, Amdt 2  
Port Heiden, AK, Port Heiden, NDB RWY 13, Amdt 5  
Port Heiden, AK, Port Heiden, NDB/DME RWY 13, Amdt 2  
Port Heiden, AK, Port Heiden, MLS RWY 5, Orig  
Port Heiden, AK, Port Heiden, GPS RWY 5, Orig  
Port Heiden, AK, Port Heiden, GPS RWY 13, Orig  
Soldotna, AK, Soldotna, VOR OR GPS-A, Amdt 6  
Soldotna, AK, Soldotna, NDB/DME RWY 7, Amdt 1  
Soldotna, AK, Soldotna, NDB RWY 25, Amdt 2  
Soldotna, AK, Soldotna, VOR/DME RNAV OR GPS RWY 7, Amdt 3, CANCELLED  
Soldotna, AK, Soldotna, VOR/DME RNAV RWY 25, Amdt 3, CANCELLED  
Soldotna, AK, Soldotna, GPS RWY 7, Orig  
Soldotna, AK, Soldotna, GPS RWY 25, Orig  
Unalakleet, AK, Unalakleet, MLS RWY 14, Orig, CANCELLED

Sedona, AZ, NDB OR GPS-A, Amdt 3, CANCELLED  
Bonifay, FL, Tri-County, NDB OR GPS-A, Amdt 1  
Stuart, FL, Witham Field, GPS RWY 12, Orig  
Stuart, FL, Witham Field, GPS RWY 30, Amdt 1  
Zephyrhills, FL, Zephyrhills Muni, GPS RWY 22, Orig  
Zephyrhills, FL, Zephyrhills Muni, GPS RWY 18, Orig  
Zephyrhills, FL, Zephyrhills Muni, GPS RWY 4, Orig  
Zephyrhills, FL, Zephyrhills Muni, GPS RWY 36, Orig  
Maquoketa, IA, Maquoketa Muni, VOR/DME RNAV OR GPS RWY 33, Orig-A, CANCELLED  
Maquoketa, IA, Maquoketa Muni, NDB RWY 15, Amdt 3  
Maquoketa, IA, Maquoketa Muni, GPS RWY 15, Orig  
Maquoketa, IA, Maquoketa Muni, GPS RWY 33, Orig  
Waterloo, IA, Waterloo Muni, GPS RWY 6, Orig  
Flemingsburg, KY, Fleming-Mason, GPS RWY 7, Orig  
Flemingsburg, KY, Fleming-Mason, GPS RWY 25, Orig  
Palmyra, NY, Palmyra Airpark, VOR OR GPS-A, Amdt 1, CANCELLED  
Price, UT, Carbon County, VOR RWY 36, Amdt 1  
Casper, WY, Natrona County Intl, GPS RWY 3, Orig  
[FR Doc. 99-7627 Filed 3-26-99; 8:45 am]  
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## FEDERAL TRADE COMMISSION

### 16 CFR Part 4

#### Appearances Before the Commission; Restrictions As To Former Members and Employees

**AGENCY:** Federal Trade Commission (FTC).

**ACTION:** Final rule.

**SUMMARY:** The Commission is amending its rule governing the appearance of former members and employees, Rule 4.1(b), to more closely track the post-employment restrictions of the criminal conflict of interest statute, 18 U.S.C. 207.

**EFFECTIVE DATE:** These amendments are effective March 29, 1999.

**FOR FURTHER INFORMATION CONTACT:** Ira S. Kaye, 202-326-2426, or Shira Pavis Minton, 202-326-2479, Attorneys, Office of the General Counsel, FTC, 600 Pennsylvania Avenue, NW., Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:** The Commission is revising paragraph (b) of Commission Rule 4.1, 16 CFR 4.1, which currently prohibits a former employee's participation, "behind-the-

scenes," in a Commission matter that had been pending under his or her official responsibility before departing the Commission, provided that the former employee had not participated in the matter personally and substantially (which includes actively supervising it), and that nonpublic documents or information about the matter had not, and would not have been likely to have, come to the former employee's attention. Under these circumstances, the rule, like 18 U.S.C. 207, will permit a former employee to render in-house assistance in connection with the representation in question (see 5 CFR 2637.201(b)(6)). The rule, however, will continue to prohibit making an appearance before, or communication to, a member or employee of the Commission with the intent to influence that person in connection with the matter.

The Commission will continue to monitor closely the post-employment activities of its former employees. The Clearance Rule will continue to require them to file clearance requests before participating in matters that were pending in the Commission before they departed, even if they had not participated in those matters, and even if they plan to render only behind-the-scenes assistance.

The Commission also is deleting, from two paragraphs, language that it had added to the rule as part of its 1998 amendments. 63 FR 15758 (April 1, 1998). First, the Commission is deleting the last sentence of paragraph (b)(5)(vii) of the Rule to clarify that, although the rule generally allows former employees to participate in rulemaking proceedings, a former "senior employee" may not communicate with or appear before a Commission employee regarding any matter, including a rulemaking proceeding, within the first year after leaving the Commission. Second, the Commission is deleting from paragraph (b)(1)(iii) the words "and the employee left the Commission within the previous three years[.]" The amendment restores the Commission's authority to prohibit participation by a former employee who left more than three years earlier, where nonpublic documents or information that would still convey a present advantage would likely have come to her attention.

These rule amendments relate solely to agency practice, and, thus, are not subject to the notice and comment requirements of the Administrative Procedure Act, 5 U.S.C. 553(a)(2), or to the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601(2).

The submissions required by the amended rule do not generally involve the "collection of information" as that term is defined by the Paperwork Reduction Act ("PRA"), 44 U.S.C. 3501-3520. Submission of a request for clearance to participate or a screening affidavit is ordinarily required only during the conduct of an administrative action or investigation involving a specific individual or entity. Such submissions are exempt from the coverage of the PRA. 5 CFR 1320.4(a)(2). To the limited extent that the rule could require a submission outside the context of an investigation or action involving a specific party, the information collection aspects of the rule have been cleared by the Office of Management and Budget and assigned OMB clearance no.3084-0047.

#### List of Subjects in 16 CFR Part 4

Administrative practice and procedure.

For the reasons set forth in the preamble, the Federal Trade Commission amends Title 16, chapter I, subchapter A, of the Code of Federal Regulations as follows:

#### PART 4—MISCELLANEOUS RULES

1. The authority citation for part 4 continues to read as follows:

**Authority:** Sec. 6, 38 Stat. 721; 15 U.S.C. 46.

##### § 4.1 [Amended]

2. Section 4.1(b)(1) introductory text is amended by adding, between the words "under" and "paragraph (b)(1)(iv)," the words "paragraph (b)(1)(ii) or".

3. Section 4.1(b)(1)(iii) is amended by removing the words "and the employee left the Commission within the previous three years".

4. Section 4.1(b)(5)(vii) is amended by removing the final sentence.

By direction of the Commission.

**Donald S. Clark,**

Secretary.

[FR Doc. 99-7519 Filed 3-26-99; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 874

[Docket No. 98P-0833]

#### Medical Devices; Exemptions From Premarket Notification; Class II Devices

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for audiometers with certain limitations. FDA is publishing this order in accordance with procedures established by the Food and Drug Administration Modernization Act of 1997 (FDAMA). **EFFECTIVE DATE:** March 29, 1999.

**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 Federal Food, Drug, and Cosmetic Act (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 (the SMDA) (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 that 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 (510(k)) 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.

On November 21, 1997, the President signed into law FDAMA (Pub. L. 105-115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list for each type of class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the **Federal Register** of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice. If FDA fails to respond to a petition under this section within 180 days of receiving it, the petition shall be deemed granted.