out further than other portions of the ATBA. The proposed ATBA amendment will permit ships in two opposing traffic patterns located just outside the boundary of the ATBA to increase the distance between them, thus increasing maritime safety in the area. The proposed amendment will not result in bringing ship traffic any closer to the reef than the other parts of the ATBA and, by reducing the potential for collisions, the amendment is beneficial for the protection of the marine environment.

The north- and east-bound vessels utilize the Gulf Stream in this area while the south- and west-bound vessels try to take advantage of countercurrents from eddies off of the Gulf Stream. The existing configuration of the ATBA near the coral reef known as ''the Elbow,'' when examined in relation to the axis of the Gulf Stream, results in a potential convergence of northeasterly bound and southwesterly bound traffic. The potential risk of collision increases when the Gulf Stream meanders closer to ''the Elbow.'' The proposed revision of the ATBA boundary will permit ships in these two opposing traffic patterns to increase the distance between them, thus increasing maritime safety in the area. A collision in this area could cause oil and other material to seep into the Florida Keys damaging marine sanctuary resources, the marine environment, and quite possibly, the recreational, tourism and fishing industries of the Florida Keys.

In March 2000, the USCG conducted a survey of mariners, who frequently travel through this area, to see whether they believed ''the Elbow'' of the ATBA to be a safety hazard for vessels traveling in that area. Close to half of the mariners surveyed felt that ''the Elbow'' created a ''pinch point'' for south- and west-bound vessels that attempt to stay out of both the ATBA and the lanes of traffic for the north- and east-bound vessels. The USCG subsequently recommended the revision of the ATBA boundary in order to increase maritime safety in the area.

Based on these recommendations, and its own draft environmental assessment of the recommendations, NOAA proposes to amend the boundary of the northernmost ATBA. This action is not expected to have a significant adverse impact on the environment.

Miscellaneous Requirements

Executive Order 12866

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

Regulatory Flexibility Act

The Chief Counsel for Regulations of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that the proposed rule is not expected to have a significant economic impact on a substantial number of small entities. The existing ATBA and the proposed boundary change do not apply to a substantial number of small entities because the ATBA only applies to tank vessels and those vessels greater than 50 meters in length. Most of the vessels subject to this rule are foreign flagged vessels that are owned or chartered by large corporations. This measure is not expected to have any impact on the small business community. Accordingly, an initial regulatory flexibility analysis was not prepared.

National Environmental Policy Act Requirements

NOAA has concluded that this regulatory action does not constitute a major federal action significantly affecting the quality of the human environment. Therefore, an environmental impact statement is not required. A draft environmental assessment has been prepared. It is available for comment (see **ADDRESSES**).

Plain Language Requirement

The President has directed all agencies to use plain language in their communications with the public, including regulations. To comply with this directive, we seek public comment on any ambiguity or unnecessary complexity arising from the language used in this rule (see **ADDRESSES**).

List of Subjects in 15 CFR Part 922

Administrative practice and procedure, Coastal zone, Marine resources, Penalties, Recreation and recreation areas, Reporting and recordkeeping requirements, Research.

Capt. Ted I. Lillestolen,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management.

Accordingly, for the reasons set forth in the preamble, 15 CFR Part 922 is proposed to be amended as follows:

PART 922—NATIONAL MARINE SANCTUARY PROGRAM REGULATIONS

1. The authority citation for part 922 continues to read as follows:

Authority: 16 U.S.C. 1431 *et seq.*

922 Appendix VII—[AMENDED]

Subpart P—Florida Keys National Marine Sanctuary

2. Appendix VII to subpart P of part 922 is amended in the table by redesignating the entries for points 23 through 51 as 24 through 52, and by revising the entries under ''In the Vicinity of the Florida Keys'' to read as follows:

Appendix VII to Subpart P of Part 922—Areas To Be Avoided Boundary Coordinates

IN THE VINCINITY OF THE FLORIDA KEYS

[Reference Charts: United States 11466, 27th Edition—September 1, 1990 and United States 11450, 4th Edition—August 11, 1990]

Point	Latitude	Longitude
1	25°45.00′N	80°06.10′W.
2	25°38.70′N	80°02.70′W.
3	25°22.00′N	80°03.00′W.
4	25°06.38′N	80°10.48′W.
5	24°56.37′N	80°19.26′W.
6	24°37.90′N	80°47.30′W.
7	24°29.20′N	81°17.30′W.
8	24°22.30′N	81°43.17′W.
9	24°28.00′N	81°43.17′W.
10	24°28.70′N	81°43.50′W.
11	24°29.80′N	81°43.17′W.
12	24°33.10′N	81°35.15′W.
13	24°33.60′N	81°26.00′W.
14	24°38.20′N	81°07.00′W.
15	24°43.20′N	80°53.20′W.
16	24°46.10′N	80°46.15′W.
17	24°51.10′N	80°37.10′W.
18	24°57.50′N	80°27.50′W.
19	25°09.90′N	80°16.20′W.
20	25°24.00′N	80°09.10′W.
21	25°31.50′N	80°07.00′W.
22	25°39.70′N	80°06.85′W.
23	25°45.00′N	80°06.10′W.

* * * * *

[FR Doc. 00–29824 Filed 11–21–00; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 864, 866, 868, 870, 872, 874, 876, 878, 884, 886, and 888

[Docket No. 99N–0035]

Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 90 days the comment period for the submission of comments regarding 3 of the 38 devices proposed for reclassification from class III into class II. The proposed rule was published in the **Federal Register** of March 15, 1999 (64 FR 12774). The agency is taking this action in order to allow more time to submit comments to FDA regarding the guidance documents that were not made available when the March 15, 1999, proposed rule was published. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of two guidance documents that are special controls for three devices.

DATES: Submit written comments on the proposed rule by February 20, 2001.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 15, 1999 (64 FR 12774), FDA published a proposed rule to reclassify 38 preamendments class III devices into class II and to establish special controls for these devices. Interested persons were given until June 14, 1999, to comment on the proposed rule.

A trade association requested that FDA reopen the comment period for 6 of the 38 devices. The request noted that FDA had not made the guidance documents that were proposed as special controls for these six devices available for comment through the agency's good guidance practices (GGP's). The request further noted that it was impossible to comment on the proposed reclassification without the guidance documents being available. Therefore, the trade association requested that FDA extend the comment period until at least 90 days after the guidance documents became publicly available for comment. In the **Federal Register** of April 19, 2000 (65 FR 20933), FDA reopened the comment period on the proposed reclassification of those six devices.

FDA also identified an additional three devices for which the agency had not issued the guidance documents proposed as special controls for comment in accordance with the GGP policy. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability for comment of two guidance documents that are special controls for three devices. Accordingly, FDA is reopening the comment period for the March 15, 1999, proposed rule to allow additional time for interested persons to comment on the following three devices:

- Indwelling blood carbon dioxide partial pressure (P_{co2}) analyzer (21 CFR 868.1150),
- Indwelling blood hydrogen ion concentration (pH) analyzer (21 CFR 868.1170), and
- Indwelling blood oxygen partial pressure (P_{o2}) analyzer (21 CFR 868.1200).

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the proposed rule only with respect to the three devices listed above by February 20, 2001. 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 31, 2000.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 00–29839 Filed 11–21–00; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[NV–032–FON; FRL–6905–6]

Clean Air Act Reclassification; Nevada—Reno Planning Area; Particulate Matter of 10 Microns or Less (PM–10)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In this action EPA proposes to find that the Reno (Washoe County) Planning Area (RPA) has not attained the PM–10 national ambient air quality standards (NAAQS) by the Clean Air Act (CAA) mandated attainment date for moderate nonattainment areas. Section 188(c)(1) of the Act established an attainment date of no later than December 31, 1994 for areas classified as moderate nonattainment areas under section 107(d)(4)(B) of the CAA. This proposed finding is based on monitored air quality data for the PM–10 NAAQS during the years 1992–1994. If EPA takes final action on this proposed finding, the RPA will be reclassified by operation of law as a serious nonattainment area under section 188(b)(2)(A) of the CAA.

DATES: Comments on this proposed finding must be received in writing by December 7, 2000.

ADDRESSES: Comments should be addressed to Manny Aquitania, U.S. Environmental Protection Agency, Region 9, Air Division, Planning Office (AIR–2), 75 Hawthorne Street, San Francisco, California 94105.

FOR FURTHER INFORMATION CONTACT: For monitoring data questions contact Manny Aquitania, U.S. EPA, Region 9, Air Division, Technical Support Office (AIR–7), 75 Hawthorne Street, San Francisco, California 94105; (415) 744–1299, aquitania.manny@epa.gov. For other questions contact Doris Lo, U.S. Environmental Protection Agency, Region 9, Air Division, Planning Office (AIR–2), 75 Hawthorne Street, San Francisco, California 94105, (415) 744–1287, lo.doris@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

A. CAA Requirements and EPA Actions Concerning Designation and Classification

On November 15, 1990, the date of enactment of the 1990 Clean Air Act Amendments, PM–10 areas meeting the qualifications of section 107(d)(4)(B) of the Act were designated nonattainment by operation of law. Once an area is designated nonattainment, section 188 of the Act outlines the process for classification of the area and establishes the area's attainment date. Pursuant to section 188(a), all PM–10 nonattainment areas were initially classified as moderate by operation of law upon designation as nonattainment. These nonattainment designations and moderate area classifications were codified in 40 CFR part 81 in a **Federal Register** notice published on November 6, 1991 (56 FR 56694). The Reno Planning Area (RPA) was designated nonattainment and classified as moderate. See 40 CFR 81.329.

States containing areas which were designated as moderate nonattainment by operation of law under section 107(d)(4)(B) were to develop and submit state implementation plans (SIPs) to