TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE JULY 1, 2001, THROUGH SEPTEMBER 30, 2001—Continued

PMA No./Docket No.	Applicant	Trade Name	Approval Date
P010023/01M–0414	SOUNDTEC, Inc.	SOUNDTEC Direct System	September 7, 2001
P000029/01M–0439	Q-Med AB	DEFLUX Injectable Gel	September 24, 2001

II. Electronic Access

Persons with access to the Internet may obtain the documents at http://www.fda.gov/cdrh/pmapage.html.

Dated: December 31, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–853 Filed 1–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0545]

''Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax'' dated October 2001. The guidance document provides the current recommendations for assessment of donor suitability and product safety for donors potentially exposed to anthrax. The guidance document applies to Whole Blood, blood components (including recovered plasma) and Source Plasma collections intended for use in transfusion or for further manufacturing into injectable products.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Recommendations for Assessment of Donor Suitability and Blood and Blood Product Safety in Cases of Possible Exposure to Anthrax'' dated October 2001. The guidance document provides the current recommendations for assessment of donor suitability and product safety for donors potentially exposed to *Bacillus anthracis*, the agent of anthrax. The guidance document applies to Whole Blood, blood components (including recovered plasma) and Source Plasma collections intended for use in transfusion or for further manufacturing into injectable products. FDA developed the recommendations in the guidance document in consultation with other Public Health Service agencies and with the Blood Safety Committee of the Department of Health and Human Services. Recommendations addressed in the guidance include: Donor deferral, product quarantine and retrieval, and notification of prior transfusion recipients.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on recommendations for assessment of donor suitability and product safety for donors potentially exposed to anthrax. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

II. Comments

The agency is soliciting public comment, but is implementing this guidance document immediately because of public health concerns. Interested persons may, at any time, submit written or electronic comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either http://www.fda.gov/cber/guidelines.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: December 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–791 Filed 1–11–02; 8:45 am]

BILLING CODE 4160–02–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0530]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the agency is making to the list of standards FDA will recognize for use in premarket reviews (FDA Recognized Consensus Standards). This publication entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 006'' (Recognition List Number: 006) will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written comments concerning this document at any time. See section VI of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of ''Modification to the List of Recognized Standards, Recognition List Number: 006'' to the Division of Small Manufacturers Assistance (DSMA), Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–443–8818. Written comments concerning this document must be submitted to the contact person (address below). Comments should be identified with the docket number found in brackets in the heading of this document. This document may also be accessed on FDA's Internet site at http://www.fda.gov/cdrh/fedregin.html. See section V of this document for electronic access to the searchable data base for the current list of ''FDA Recognized Consensus Standards,'' including Recognition List Number: 006 modifications, and other standards related information.

FOR FURTHER INFORMATION CONTACT: To comment on this document and/or to recommend additional standards for recognition: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 156.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards, developed by international and national organizations, for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** ofFebruary 25, 1998 (63 FR 9561), FDA announced the availability of guidance entitled ''Recognition and Use of Consensus Standards.'' This notice described how FDA will implement its standards program recognizing the use of certain standards and provided the initial list of recognized standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617); July 12, 1999 (64 FR 37546); November 15, 2000 (65 FR 69022); and May 7, 2001 (66 FR 23032), FDA modified its initial list of recognized standards. These notices described the addition, withdrawal, and revision of certain standards recognized by FDA. When these notices were published, the agency maintained ''html'' and ''pdf'' versions of the list of ''FDA Recognized Consensus Standards.'' Both versions were publicly accessible at the agency's Internet site. The agency maintains the current list in a searchable data base accessible to the public. See section V of this document for electronic access information.

II. Discussion of Modifications to the List of Recognized Standards, Recognition List Number: 006

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews for devices. FDA will incorporate these modifications in the list of ''FDA Recognized Consensus Standards'' in the agency's searchable data base. FDA will use the term ''Recognition List Number: 006'' to identify: (1) Supplementary information sheets for standards added to the list for the first time, (2) standards added to replace withdrawn standards, (3) still recognized standards for which minor revisions are made to clarify the application of the standards, and (4) standards withdrawn with no replacement.

At the end of this notice, FDA lists modifications the agency is making that involve: (1) The initial addition of standards not previously recognized by FDA and (2) the addition of standards in conjunction with the withdrawal of other standards that are replaced by these later, amended, or different standards.

In this section, FDA describes: (1) Modifications that involve the withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the addition of certain recognized standards with revisions to the supplementary information sheets involving changes in significant applications of the standards.

A. Anesthesia

1. In the supplementary information sheet for IEC 60601–3–1:1996–08, identified under previous item 11, a minor change is made to the contact person. This standard remains recognized and identified under current item 11.

2. In the supplementary information sheet for ASTM F1456–92, identified under previous item 24, a minor change is made to the contact person. This standard remains recognized and identified under current item 24.

3. In the supplementary information sheet for ASTM F1462–93, identified under previous item 25, a minor change is made to the contact person. This standard remains recognized and identified under current item 25.

4. In the supplementary information sheet for ISO 7767:1997, identified under previous item 32, a minor change is made to the contact person. This standard remains recognized and identified under current item 32.

5. In the supplementary information sheet for ISO 9918:1993, identified under previous item 33, a minor change is made to the contact person. This standard remains recognized and identified under current item 33.

B. Biocompatibility

1. ASTM F1904–98 is withdrawn under previous item 44. ASTM F1904–98e1 is added under current item 52.

2. ASTM E1372–95 is withdrawn under previous item 33. ASTM E1372–95 (1999) is added under current item 53.

3. ISO/AAMI/ANSI 10993–5:1998 is withdrawn under previous item 29. ANSI/AAMI/ISO 10993–5:1999 is added under current item 54.

4. ISO/AAMI/ANSI 10993–6:1995 is withdrawn under previous item 18. ANSI/AAMI/ISO 10993–6:1994 is added under current item 55.

C. Cardiovascular/Neurology

1. ASTM F138–97 is withdrawn under previous item 9. ASTM F138–00 is added under current item 34.

2. ASTM F562–95 is withdrawn under previous item 11. ASTM F562–00 is added under current item 35.

3. ASTM F136–98 is withdrawn under previous item 23. ASTM F136–98e1 is added under current item 36.

4. IEC 60601–2–23:1993 is withdrawn under previous item 26. IEC 60601–2–

23 (1999–12) is added under current item 37.

5. IEC 60601–2–34 (1994–12) is withdrawn under previous item 27. IEC 60601–2–34 (2000–10) is added under current item 38.

6. ASTM F647–94 is withdrawn under previous item 31. ASTM F647–94 (2000) is added under current item 39.

D. Dental/ENT

1. In the supplementary information sheet for ISO 7494:1996, identified under previous item 74, a minor change is made to the contact person. This standard remains recognized and identified under current item 74.

2. In the supplementary information sheet for ISO 7785–1:1997, part 1, identified under previous item 75, a minor change is made to the contact person. This standard remains recognized and identified under current item 75.

3. In the supplementary information sheet for ISO 7785–2:1995, part 2, identified under previous item 76, a minor change is made to the contact person. This standard remains recognized and identified under current item 76.

4. In the supplementary information sheet for ISO 9168:1991, identified under previous item 78, a minor change is made to the contact person. This standard remains recognized and identified under current item 78.

5. In the supplementary information sheet for ISO 13294:1997, identified under previous item 84, a minor change is made to the contact person. This standard remains recognized and identified under current item 84.

E. General

1. IEC 60601–1–1:1992–06 amendment 1, 1995–11 is withdrawn under previous item 5. IEC 60601–1–1:2000 is added under current item 27.

2. IEC 60601–1–2, First Edition 1993–04, is withdrawn under previous item 6. IEC 60601–1–2, Second Edition 2001, is added under current item 28.

3. ASTM D–4169/1993 is withdrawn under previous item 17. ASTM D–4169:1999 was recognized by ''Sterility'' in the November 15, 2001, recognition list 004.

F. General Hospital/General Plastic Surgery

1. In the supplementary information sheet for IEC 60601–2–21, identified under previous item 09, a minor change is made to the contact person. This standard remains recognized and identified under current item 09.

2. In the supplementary information sheet for IEC 60601–2–38, identified under previous item 10, a minor change is made to the contact person. This standard remains recognized and identified under current item 10.

3. In the supplementary information sheet for IEC 60601–2–19/1996–10, identified under previous item 29, the a minor change is made to contact person. This standard remains recognized and identified under current item 29.

4. In the supplementary information sheet for IEC 60601–2–20/1996–10, identified under previous item 32, the a minor change is made to contact person. This standard remains recognized and identified under current item 32.

5. ISO 8536–4, First Edition 1987–11–01, is withdrawn under previous item 17. ISO 8536–4, Second Edition 1998–02–15, is added under current item 75.

6. ISO 1135–4, First Edition 1987–12–01, is withdrawn under previous item 19. ISO 1135–4, Second Edition 1998–03–15, is added under current item 76.

7. ASTM F1862–98 is withdrawn under previous item 36. ASTM F1862–00a is added under current item 77.

8. ASTM F1670–97 is withdrawn under previous item 39. ASTM F1670–98 is added under current item 78.

9. ISO 594/2, First Edition 1991–05–01, is withdrawn under previous item 12. ISO 594–2:1998 is added under current item 79.

10. ASTM E1112–86 (reapproved 1991) is withdrawn under previous item 02. ASTM E1112–00 (reapproved 1991) is added under current item 80.

G. ObGyn/Gastroenterology

1. ASTM F1518–94 is withdrawn under previous item 22. ASTM F1518–00 is added under current item 23.

2. ASTM F623–89 is withdrawn under previous item 3. ASTM F623–99 is added under current item 24.

3. AAMI HF18–93 is withdrawn under previous item 18. ANSI/AAMI HF18–2001 is added under current item 25.

H. Orthopaedic

1. ASTM F67–95 is withdrawn under previous item 1. ASTM F67–00 is added under current item 123.

2. ASTM F86–91 is withdrawn under previous item 3. ASTM F86–01 is added under current item 124.

3. ASTM F139–96 is withdrawn under previous item 7. ASTM F139–00 is added under current item 125.

4. ASTM F366–82 (R1993) is withdrawn under previous item 8. ASTM F366–82 (2000) is added under current item 126.

5. ASTM F562–95 is withdrawn under previous item 11. ASTM F562–00 is added under current item 127.

6. ASTM F604–94 is withdrawn under previous item 15 with no replacement. ASTM discontinued it in 2001.

7. ASTM F688–95 is withdrawn under previous item 20. ASTM F688–00 is added under current item 128.

8. ASTM F745–95 is withdrawn under previous item 21. ASTM F745–00 is added under current item 129.

9. ASTM F799–96 is withdrawn under previous item 25. ASTM F799–99 is added under current item 130.

10. ASTM F1044–95 is withdrawn under previous item 30. ASTM F1044–99 is added under current item 131.

11. ASTM F1088–87 (1992) is withdrawn under previous item 31. ASTM F1088–87 (1992) e1 is added under current item 132.

12. ASTM F1108–97 is withdrawn under previous item 34. ASTM F1108–97a is added under current item 133.

13. ASTM F1295–97 is withdrawn under previous item 39. ASTM F1295–97a is added under current item 134.

14. ASTM F1341–92 is withdrawn under previous item 41. ASTM F1341–99 is added under current item 135.

15. ASTM F1472–93 is withdrawn under previous item 44. ASTM F1472–00 is added under current item 136.

16. ASTM F1501–95 is withdrawn under previous item 45. ASTM discontinued it in 2000. It was replaced with ASTM F1147–99 item 107.

17. ASTM F1537–94 is withdrawn under previous item 46. ASTM F1537–00 is added under current item 137.

18. ASTM F1541–94 is withdrawn under previous item 47. ASTM F1541–00 is added under current 138.

19. ASTM F1580–95 is withdrawn under previous item 48. ASTM F1580–95e1 is added under current item 139.

20. ASTM F1582–95 is withdrawn under previous item 49. ASTM F1582–98 is added under current item 140.

21. ASTM F1612–95 is withdrawn under previous item 52. ASTM F1612–95 (2000) is added under current item 141.

22. ASTM F1658–95 is withdrawn under previous item 53. ASTM discontinued it in 2000. It was replaced with ASTM F1044–99, item 131.

23. ASTM F1672–95e1 is withdrawn under previous item 55. ASTM F1672–95 (2000) is added under current item 142.

24. ISO 7153–1:1991 is withdrawn under previous item 77. ISO 7153–1:1991/amended 1:1999 is added under current item 143.

25. ASTM F138–97 is withdrawn under previous item 89. ASTM F138–00 is added under current item 144.

26. ASTM F565–85 (1996) e1 is withdrawn under previous item 92. ASTM F565–00 is added under current item 145.

27. ASTM F603–83 (1995) is withdrawn under previous item 94. ASTM F603–00 is added under current item 146.

28. ASTM F1539–95 is withdrawn under previous item 95. ASTM discontinued it in 2000. It was replaced with ASTM F564–00, item 156.

29. ASTM F620–97 is withdrawn under previous item 96. ASTM F620–00 is added under current item 147.

30. ASTM F648–98 is withdrawn under previous item 99. ASTM F648–00 is added under current item 148.

31. ASTM F746–87 (1994) is withdrawn under previous item 100. ASTM F746–87 (1999) is added under current item 149.

32. ASTM F983–86 (1996) is withdrawn under previous item 102. ASTM F983–86 (2000) is added under current item 150.

33. ASTM F1540–95 is withdrawn under previous item 103. ASTM discontinued it in 2000. It was replaced with ASTM F564–00, item 156.

34. ASTM F1091–91 (1996) is withdrawn under previous item 105. ASTM F1091–91 (2000) is added under current item 151.

35. ASTM F1691–96 is withdrawn under previous item 106. ASTM discontinued it in 2001. It was replaced with ASTM F543–01, item 157.

36. ASTM F1160–98 is withdrawn under previous item 108. ASTM F1160–00 is added under current item 152.

37. ASTM F1264–99 is withdrawn under previous item 110. ASTM F1264–00 is added under current item 153.

38. ASTM F1350–91 (1996) is withdrawn previous item 112. ASTM F1350–91 (2001) is added under current item 154.

39. ISO 7207–2:1994 is withdrawn under previous item 122. ISO 7207–2:1998 is added under current item 155.

I. Physical Medicine

1. ISO 7176–1:1986 is withdrawn under previous item 16. ISO 7176–1:1999 is added under current item 158.

2. ISO 7176–2:1990 is withdrawn under previous item 17. ISO 7176–2:2001 is added under current item 159.

3. ANSI/RESNA WC/Vol. 2–1998, section 21: Requirements and Test Methods for Electromagnetic Compatibility—new item #160.

J. Radiology

1. AIUM—1994 is withdrawn under previous item 4. AIUM—Medical Ultrasound Safety (R1999) is added under current item 66.

2. In the supplementary information sheet for IEC 60806, identified under previous item 6, the title has been changed. This standard remains recognized and identified under current item 6.

3. NEMA MS–1–1988 is withdrawn under previous item 10. NEMA MS–1–1998 (R2000) is added under current item 67.

4. NEMA MS–4–1989 is withdrawn under previous item 13. NEMA MS–4 (R1998) is added under current item 68.

5. NEMA MS6–2000 is withdrawn under previous item 15. NEMA MS6–2000 is added under current item 69.

6. NEMA PS3 (set), DICOM Set is withdrawn under previous item 19. NEMA PS3 (set), DICOM Set is added under current item 70.

7. NEMA UD 2–2998, revision 2 is withdrawn under previous item 20. NEMA UD 2–1998 revision 2 is added under current item 71.

8. NEMA UD 3–1998, revision 1 is withdrawn under previous item 21. NEMA UD 3–1998 revision 1 is added under current item 72.

9. In the supplementary information sheet(s) for IEC 60601–2–19, identified under previous item 36, the date has been changed. This standard remains recognized and identified under current item 36.

10. In the supplementary information sheet(s) for AIUM–AOMS, identified under previous item 44, the title has been changed. This standard remains recognized and identified under current item 44.

11. In the supplementary information sheet(s) for IEC 61303, identified under previous item 49, a minor change is made to the Standard Development Organization. This standard remains recognized and identified under current item 49.

12. In the supplementary information sheet(s) for IEC 61145, identified under previous item 51, the name of the Standards Development Organization has been changed. This standard remains recognized and identified under current item 51.

13. In the supplementary information sheet(s) for UL–544, identified under previous item 52, the date has been changed. This standard remains recognized and identified under current item 52.

14. UL–122 is withdrawn under previous item 61. UL–122 (2001) is added under current item 73.

15. NEMA MS–7–1998 is withdrawn under previous item 16. NEMA MS–7–1998 is added under current item 74.

K. Sterility

1. AAMI/ANSI ST34:1991 is withdrawn under previous item 15. ANSI/AAMI/ISO 14161:2000 is added under current item 70.

2. In the supplementary information sheet for ANSI/AAMI ST24:1999, identified under previous item 38, the title and the contact person have been changed. This standard remains recognized and identified under current item 38.

3. In the supplementary information sheet for ANSI/AAMI ST37:1996, identified under previous item 47, the title and the contact person have been changed. This standard remains recognized and identified under current item 47.

4. In the supplementary information sheet for ANSI/AAMI ST41:1999, identified under previous item 49, the title and the contact person have been changed. This standard remains recognized and identified under current item 49.

III. List of Recognized Standards

FDA maintains the agency's current list of ''FDA Recognized Consensus Standards'' in a searchable data base that may be accessed directly at FDA's Internet site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. FDA will incorporate the modifications and minor revisions described in this notice into the data base and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective.

FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

IV. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (address above). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

V. Electronic Access

In order to receive ''Guidance on the Recognition and Use of Consensus Standards'' via your fax machine, call the CDRH Facts-On-Demand system at

800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of ''Guidance onthe Recognition and Use of Consensus Standards'' may also do so by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes this guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 006'' will be available on the CDRH home page. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable data base for ''FDA Recognized Consensus Standards,'' may be accessed through hyper links at http://www.fda.gov/cdrh/stdsprog.html. This **Federal Register** notice of modifications in FDA's recognition of consensus standards will be available, upon publication, at http://www.fda.gov/cdrh/fedregin.html.

VI. Submission of Comments and Effective Date

Interested persons may, at any time, submit to the contact person (address above) written comments regarding this document. 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 will be considered in determining whether to amend the current listing of ''Modifications to the List of Recognized Standards, Recognition list: 006.''

The recognition of standards announced in this notice of modifications will become effective on January 14, 2002.

VII. Listing of New Entries

The listing of new entries and consensus standards added as ''Modifications to the List of Recognized Standards,'' under Recognition List Number: 006, is as follows:

Item Number	Title of Standards	Reference Number and Date
	Biocompatibility	
52	Standard Practice for Testing for Biological Responses to Particles In Vivo	ASTM F1904–98e1
53	Standard Test Method for Conducting a 90-Day Oral Toxicity Study in Rats	ASTM E1372–95 (1999)
54	Biological Evaluation of Medical Devices—Part 5: Tests for Cytotoxicity: In Vitro Methods	ANSI/AAMI/ISO 10993–5:1999
55	Biological Evaluation of Medical Device—Part 6: Test for Local Effects After Implantation	ANSI/AAMI/ISO 10993–6:1994
	Cardiovascular/Neurology	
34	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants	ASTM F138–00
35	Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications	ASTM F562–00
36	Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstital) Alloy (UNS R56401) for Surgical Implant Applications	ASTM F136–98e1
37	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Transcutaneous Partial Pressure Monitoring Equipment	IEC 60601–2–23 (1999–12)
38	Medical Electrical Equipment-Part 2: Partial Requirements for the Safety of Direct Blood Pressure Monitoring Equipment	IEC 60601–2–34 (2000–10)
39	Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application	ASTM F647–94 (2000)
40	Nonautomated Sphygmomanometers	ANSI/AAMI SP9:1994
41	Diagnostic Electrocardiographic Devices	ANSI/AAMI EC11:1991
42	Cardiac Monitors, Heart Rate Meters, and Alarms	ANSI/AAMI EC13:1992
43	Ambulatory Electrocardiographs	ANSI/AAMI EC38:1998
44	Blood Pressure Transducers	ANSI/AAMI BP22:1994
	General	
27	Medical Electrical Equipment—Part 1: General Requirements for Safety; Safety Requirements for Medical Electrical Systems	IEC 60601–1–1:2000
28	Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility—Requirements and Tests	IEC 60601–1–2, Second Edition, 2001
29	Human Factors Design Process for Medical Devices	ANSI/AAMI HE74–2001
	General Hospital/ General Plastic Surgery	
62	Infusion Equipment for Medical Use—Part 6: Freeze Drying Closures for Infusion Bottles	ISO 8536–6, First Edition, 1996–04–01
63	Infusion Equipment, Caps Made of Aluminum-Plastic Combinations for Infusion Bottles	ISO 8536-7, Second Edition, 1999-09-01
64	Infusion Equipment for Medical Use—Part 3: Aluminum Caps for Infusion Bottles	ISO 8536–3, Second Edition, 1999–09–01
65	Infusion Equipment for Medical Use—Part 2: Closures for Infusion Bottles	ISO 8536–2, First Edition, 1992–09–15
66	Infusion Equipment for Medical Use—Part 1: Infusion Glass Bottles	ISO 8536–1, Second Edition, 2000–06–01
67	Infusion Equipment for Medical Use—Part 5: Burette Type Infusion Sets	ISO 8536–5, First Edition, 1992–01–15

Item Number	Title of Standards	Reference Number and Date
68	Sterile Hypodermic Syringes for Single Use—Part 2: Syringes for Use With Powder-Driven Syringes Pumps	ISO 7886–2, First Edition, 1996–05–15
69	Stainless Steel Needle Tubing for Manufacture of Medical Devices	ISO 9626, First Edition, 1991–09–11
70	Standard Specification of Phase Change—Type Disposable Thermometer for Intermittent Determination of Human Temperature	ASTM E825–87
71	Standard Specification of Clinical Thermometers (Maximum Self-Registering, Mercury-In-Glass)	ASTM E667–86
72	Sterile, Single-Use Intravascular Catheters—Part 5: Over-Needle Peripheral Catheters, Amendment 1	ISO 10555–5, First Edition, 1996–06–15
73	Standard Specification for Clinical Thermometers Probe Covers and Sheaths	ASTM E1104–86
74	Standard Specification for Clinical Thermometers for Intermittent Determination of Patient Temperature	ASTM E1965–98
75	Infusion Equipment for Medical Use—Part 4: Infusion Sets for Single Use, Gravity Feed	ISO 8536–4, Second Edition, 1998–02–15
76	Transfusion Equipment for Medical Use—Part 4: Transfusion Sets for Single Use	ISO 1135–4, Second Edition, 1998–03–15
77	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)	ASTM F1862–00a
78	Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood	ASTM F1670–98
79	Conical Fittings With a 6 Percent (Luer) Taper for Syringes, Needles and Certain Other Medical Equipment—Part 2: Lock Fittings	ISO 594–2:1998
80	Standards Specification for Electronic Thermometers for Intermittent Determination of Patient Temperature	ASTM E1112–00 (reapproved 1991)
81	Standard Specification for Direct-Reading Liquid Crystal Forehead Thermometers	ASTM E1601–85
	In Vitro Devices	
54	Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials Second Edition; Approved Guideline	NCCLS: D12–A2
55	Procedures for the Handling and Processing of Blood Specimens; Approved Guideline; Second Edition	NCCLS: H18–A2
56	Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobiacally; Approved Standard; Fifth Edition	NCCLS: M7–A5
57	Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard; Seventh Edition	NCCLS: M2–A7
58	Procedures for the Collection of Arterial Blood Specimens; Approved Standard	NCCLS: H1–A3
59	Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard	NCCLS: AUTO2–A
60	Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard	NCCLS: AUTO1–A
61	Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard	NCCLS: AUTO3–A
	Obstetrics–Gynecology/Gastroenterology	
23	Standard Practice For Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of Hollow Viscera	ASTM F1518–00
24	Standard Performance Specifications for Foley Catheters	ASTM F623–99
25	Electrosurgical Devices	ANSI/AAMI HF18–2001
	Ophthalmic	
27	Ophthalmic Implants—Intraocular Lenses—Part 7: Clinical Investigations	ISO 11979–7:2001
28	Ophthalmic Optics—Contact Lens Care Products—Microbiological Requirements and Test Methods for Products and Regimens for Hygienic Management of Contact Lenses	ISO 14729:2001
29	Ophthalmic Optics—Contact Lens Care Products—Antimicrobial Preservative Efficacy Testing and Guidance on Determining Discard Date	ISO 14730:2000
	Orthopaedic	
123	Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)	ASTM F67–00
124	Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	ASTM F86–01
125	Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Sheet and Strip for Surgical Implants	ASTM F139–00
125	Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Sheet and Strip for Surgical Implants	ASTM F139–00
126	Standard Specification for Fixation Pins and Wires	ASTM F366–82 (2000)
127	Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications	ASTM F562–00
128	Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)	ASTM F688–00
129	Standard Specification for 18 Chromium-12.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications	ASTM F745–00
130	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	ASTM F799–99
131	Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	ASTM F1044-99
132	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	ASTM F1088–87 (1992) e1
133	Standard Specification for Ti6A14V Alloy Castings for Surgical Implants (UNS R56406)	ASTM F1108–97a
134	Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700)	ASTM F1295–97a
135	Standard Specification for Unalloyed Titanium Wire UNS R50250, UNS R50400, UNS R50550, UNS R50700 for Surgical Implant Applications	ASTM F1341–99
136	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications	ASTM F1472–00

Item Number	Title of Standards	Reference Number and Date
137	Standard Specification for Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	ASTM F1537–000
138	Standard Specification and Test Methods for External Skeletal Fixation Devices	ASTM F1541–00
139	Standard Specification for Titanium and Titanium-6 Percent Aluminum-4 Percent Vanadium Alloy Powders for Coatings of Surgical Implants	ASTM F1580–95e1
140	Standard Terminology Relating to Spinal Implants	ASTM F1582–98
141	Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion	ASTM F1612–95 (2000)
142	Standard Specification for Resurfacing Patellar Prosthesis	ASTM F1672–95 (2000)
143	Surgical Instruments—Metallic Materials—Part 1: Stainless Steel	ISO 7153–1:1991/ Amd.1:1999
144	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	ASTM F138–00
145	Standard Practice for Care and Handling of Orthopedic Implants and Instruments	ASTM F565–00
146	Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application	ASTM F603–00
147	Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants	ASTM F620–00
148	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	ASTM F648–00
149	Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	ASTM F746–87 (1999)
150	Standard Practice for Permanent Marking of Orthopaedic Implant Components	ASTM F983–86 (2000)
151	Standard Specification for Wrought Cobalt-Chromium Alloy Surgical Fixation Wire	ASTM F1091–91 (2000)
152	Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	ASTM F1160–00
153	Standard Specification and Test Methods for Intramedullary Fixation Devices	ASTM F1264–00
154	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)	ASTM F1350–91 (2000)
155	Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 2: Articulating Surfaces Made of Metal, Ceramic and Plastics	ISO 7207–2:1998
156	Standard Specification and Test Methods for Metallic Bone Staples	ASTM F564–00
157	Standard Specification and Test Methods for Metallic Medical Bone Screws	ASTM F543–01
	Physical Medicine	
158	Wheelchairs—Part 1: Determination of Static Stability	ISO 7176–1:1999
159	Wheelchairs—Part 2: Determination of Dynamic Stability of Electric Wheelchairs	ISO 7176–2:2001
160	Requirements and Test Methods for Electromagnetic Compatibility	ANSI/RESNA WC/Vol.2–1998, Section 21
	Radiology	
63	Medical Electrical Equipment—Part 2–43: Particular Requirements for the Safety of X-ray Equipment for Interventional Procedures	IEC 60601–2–43–Ed. 1.0
64	Medical Electrical Equipment—Part 2–45: Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotatic Devices	IEC 60601–2–45–Ed. 20
65	Standard Test Method for Measurement of Magnetically Induced Displacment Force on Passive Implants in the Magnetic Resonance Environment	ASTM F2052–00
66	Medical Ultrasound Safety (R1999)	AIUM
67	Determination of Signal to Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images	NEMA MS–1 (R–2000)
68	Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Device	NEMA MS–4 (R1998)
69	Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images	NEMA MS6–2000
70	Digital Imaging and Communications in Medicine-Set Includes PS3.1 Through PS3.14	NEMA PS3 (Set), DICOM Set
71	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	NEMA UD 2–1998 (revision 2)
72	Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment	NEMA UD 3–1998 (revision 1)
73	Medical Electrical Equipment: Radionuclide Calibrators—Particular Methods for Describing Performance Calibration and Usage of Ionization	IEC 61303 (1994–10)
74	Calibration and Usage of Ionization Chamber Systems for Assay of Radionuclides	IEC 61145 (1992-05)
75	Standard for Safety of Photographic Equipment—Fourth Edition	UL–122 (2001)
76	Measurement Procedure for Time-Varying Gradient Fields (dB/dt) for Magnetic Resonance Imaging Systems	NEMA MS7–1998
	Software	
7	Medical Device Software—Software Life Cycle Processes	ANSI/AAMI SW68:2001
	Sterility	
70	Sterilization of Health Care Products—Biological Indicators—Guidance for the Selection, Use and Interpretation of Results, Second Edition	ANSI/AAMI/ISO 14161–2000

Dated: December 18, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–852 Filed 1–11–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Threemile Canyon Farms Multi-Species Candidate Conservation Agreement with Assurances

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent.

SUMMARY: Pursuant to the National Environmental Policy Act, this notice advises the public that the U.S. Fish and Wildlife Service (Service), in cooperation with the Oregon Department of Fish and Wildlife (ODFW), The Nature Conservancy (TNC), and Portland General Electric (PGE), intends to gather information necessary to prepare an environmental document (environmental assessment or environmental impact statement) regarding the proposed Threemile Canyon Farms Multi-Species Candidate Conservation Agreement with Assurances (MSCCAA) and issuance of an enhancement of survival permit under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA). Threemile Canyon Farms is the potential permit applicant.

The Service is furnishing this notice in order to: (1) Advise other Federal and State agencies, affected tribes, and the public of our intentions; (2) announce the initiation of a 30-day public scoping period; and (3) to obtain suggestions and information on the scope of issues to be included in the environmental document.

DATES: Written comments from all interested parties must be received on or before February 13, 2002.

ADDRESSES: Comments should be addressed to Kemper McMaster, State Supervisor, USFWS, 2600 SE 98th Ave., Suite 100, Portland, OR 97266, telephone (503) 231–6179, facsimile (503) 231–6195.

FOR FURTHER INFORMATION CONTACT: Kemper McMaster, (503) 231–6179.

SUPPLEMENTARY INFORMATION: Candidate Conservation Agreements with Assurances contain a strategy for covered lands and activities that demonstrate an applicant's contribution to preclude or remove the need to list a covered species as threatened or endangered under the Act. In return, the applicant is provided with regulatory certainty that they will not be required to provide additional conservation measures should any of the covered species become listed under the ESA in the future. The MSCCAA will cover approximately 93,000 acres near Boardman, Oregon, including a 23,000-acre wildlife conservation area managed by TNC and property owned by PGE located within the plan boundaries. The primary goal of the MSCCAA is to implement a variety of habitat conservation measures for the following covered species: the Washington ground squirrel (*Spermophilus washington*), ferruginous hawk (*Buteo regalis*), loggerhead shrike (*Lanius ludovicianus*), grasshopper sparrow (*Ammodramus savannarum*), and the sage sparrow (*Amphispiza belli*). Conservation measures will focus on restoration and re-establishment of native plant communities including sagebrush and bitterbrush steppe along with grassland species such as needle and thread (*Stipa spp.*). Other measures include control of exotic species and implementation monitoring. Potential covered activities include: mechanized farming and dairy operations; product transportation; road construction, use and maintenance; site preparation; fertilizer application; fire suppression; prescribed burning and other agricultural or habitat restoration activities.

The Service will conduct an environmental review of the Plan and prepare an environmental document. The review will analyze the proposal, as well as a full range of reasonable alternatives, and the associated impacts of each. Should information become available during the scoping process that indicates the likelihood of significant impacts from the proposed project, an Environmental Impact Statement will be prepared. Otherwise, an Environmental Assessment will be prepared. Comments and suggestions are invited from all interested parties to ensure the full range of issues related to this proposed action are identified. Comments, or questions should be addressed to the Service at the address or telephone number provided above.

The environmental review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*), National Environmental Policy Act Regulations 40 CFR (1500–1508), other appropriate Federal laws and regulations, and policies and procedures of the Service for compliance with those regulations.

Dated: January 8, 2002.

Rowan W. Gould,

Deputy Regional Director, Fish and Wildlife Service, Region 1, Portland, Oregon.

[FR Doc. 02–849 Filed 1–11–02; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

Agency Information Collection Activities: Proposed Collection, Comment Request

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Notice of an extension of a currently approved information collection (OMB Control Number 1010–0122).

SUMMARY: To comply with the Paperwork Reduction Act (PRA) of 1995, we are inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) is titled ''Filing Sureties.''

DATES: Submit written comments on or before March 15, 2002.

ADDRESSES: Submit written comments to Carol P. Shelby, Regulatory Specialist, Minerals Management Service, Minerals Revenue Management, PO Box 25165, MS 320B2, Denver, Colorado 80225. If you use an overnight courier service, MMS's courier address is Building 85, Room A–614, Denver Federal Center, Denver, Colorado 80225.

FOR FURTHER INFORMATION CONTACT: Carol P. Shelby, telephone (303) 231–3151, FAX (303) 231–3385.

SUPPLEMENTARY INFORMATION:

Title: Filing Sureties.

OMB Control Number: 1010–0122.

Bureau Form Number: Forms MMS–4435 and 4436.

Abstract: The Department of the Interior (DOI) is responsible for matters relevant to mineral resource development on Federal and Indian lands and the Outer Continental Shelf (OCS). The Secretary of the Interior (Secretary) is responsible for managing the production of minerals from Federal and Indian lands and the OCS, collecting royalties from lessees who produce minerals, and distributing the funds collected in accordance with applicable laws. The Secretary also has an Indian trust responsibility to manage Indian lands and seek advice and information from Indian beneficiaries. MMS performs the royalty management functions and assists the Secretary in