I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change amends Exchange Rules 4.11 and 4.12 concerning position and exercise limits, raising those limits from 2000 to 3000 option contracts.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The purpose of this proposed increase in position and exercise limits from 2,000 to 3,000 contracts is to add to market depth and liquidity.

In 1978 the Special Study of the Options Markets recommended that existing Exchange rules, which limited the size of options positions held by market participants, be reviewed and that their relaxation or elimination be considered. As a result of re-examination of position limits, as suggested in that Study, the Exchange proposed rule changes which were adopted in October of 1980 to raise position and exercise limits from 1,000 to 2,000 contracts. In view of the increased use of the options markets and the experience gained during the two years since the position limits were increased in 1980, the Exchange believes that it is appropriate at this time to increase the position and exercise limits from 2,000 to 3,000 contracts.

The Commission made the following statements in its release approving the position and exercise limit increase in 1980. (Release No. 34–17237) The Exchange believes that these statements also apply to this proposed increase to 3000 contracts.

"* * * there is substantial reason to believe that the current ceiling serves to constrict significantly the options activities of certain market professionals and institutions, possibly to the detriment of market depth and liquidity. In addition, the Commission believes that the surveillance capabilities of the options exchanges with respect to large options positions should minimize the possibility of manipulation. Finally, the Commission believes that the information and experience gained from approval of the proposed modification will enhance the ability of the options exchanges and the Commission to responsibly propose and effectively evaluate possible further modifications * * *"

A major concern in any raising of position and exercise limits is the greater potential for "short squeezes" that will result. A "short squeeze" can occur when there is an accumulation of large option positions, which are exercised day after day, so that uncovered option writers who are assigned to deliver stock on the exercises must buy that stock at increasingly higher prices because fewer shares are available. As the Exchange conveyed in its last position limit increase filing (SR–CBOE–80–22), the theoretical peril of a short squeeze is created by the size of the uncovered short interest in an option class. Each option exchange has the ability to impose limitations on uncovered writing or on the uncovering of existing short positions. (See, for example, Exchange Rules 4.15, 4.16 and 15.3) In addition, the Options Clearing Corporation under appropriate circumstances can require cash settlement. In sum, "short squeezes" can be handled directly, rather than indirectly, by means of position limits.

Finally, position limits cannot be justified as a protection against financial exposure. While unhedged larger positions do entail larger financial risks, position limits are cumbersome and ineffective mechanisms for limiting those risks. Rather, those rules which have been designed specifically to limit risk exposure should be used for this purpose, namely, suitability, margin, and net capital rules.

The basis for this proposed rule change is section 6(b)(5), in that the change would increase market depth and liquidity, which is in the public interest, while continuing to protect investors from manipulative activities.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose a burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, at the above address. Copies of such filing will also be available for inspection and coping at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted within 21 days after the date of this publication.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

Dated: November 1, 1982.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-30718 Filed 11-5-82; 8:45 am]

BILLING CODE 8010-01-M

[File No. 1-7976]

Xonics, Inc., Class A Common, $.10 Par Value; Application to Withdraw from Listing and Registration

November 2, 1982.

The above named issuer has filed an application with the Securities and Exchange Commission pursuant to Section 12(d) of the Securities Exchange Act of 1934 ("Act") and Rule 12d2–2(d) promulgated thereunder, to withdraw the specified security from listing and

registration on the Pacific Stock Exchange, Inc. ("PSE").

The reasons alleged in the application for withdrawing this security from listing and registration include the following:

Xonics, Inc. ("Company") is listed and registered on the PSE. The Company wishes to list its security on NASDAQ because the Company desires to gain national exposure. In this regard, the Company has determined that the opportunity for national exposure would be enhanced if the Company were listed on NASDAQ and removed from listing and registration on the PSE.

Any interested person may, on or before November 24, 1982, submit by letter to the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 82-30708 Filed 11-8-82; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF THE TREASURY

Advisory Committee on the International Monetary System; Continuation

Pursuant to the Federal advisory Committee Act of October 6, 1972, (Pub. L. 92-463, 86 Stat. 770-776, 5 U.S.C. App. I, Supp. II) the Department of the Treasury announces the continuation of the following advisory committee:

Title: The Advisory Committee on the International Monetary System.

Purpose: The Committee, composed of representatives from banking, industry, labor and the academic community, as well as former government officials, discusses major issues concerning the effective functioning of the international monetary system and potential areas for improvement, advising the Secretary of the Treasury on these questions in the International Monetary Fund and in other forums.

Statement of Public Interest: The world economy is in a period of significant change affecting, among other things, the operations of the international monetary system. It is important that the Secretary of the Treasury continue to receive the advice and recommendations of the Advisory Committee in this period. The depth and breadth of the members' experience in international monetary affairs cannot be duplicated from sources within the Treasury nor from another existing advisory committee.

Authority for this committee will expire August 21, 1984, unless formally extended by the Secretary of the Treasury.

Dated: August 18, 1982.

Beryl W. Sprinkel,

Under Secretary for Monetary Affairs.

[FR Doc. 82-30716 Filed 11-8-82; 8:45 am]

BILLING CODE 4810-25-M

VETERANS ADMINISTRATION

Station Committee on Educational Allowances; Meeting

Notice is hereby given pursuant to Section V, Review Procedure and Hearing Rules, Station Committee on Educational Allowances that on November 23, 1982, at 1:00 p.m., the Veterans Administration Regional Office, St. Petersburg, Florida, Station Committee on Educational Allowances, shall, at the Federal Building, Room 654, 144 1st Avenue South, St. Petersburg, Florida, conduct a hearing to determine whether Veterans Administration benefits to all eligible persons enrolled in an Apprenticeship Training Program at Vero Beach Carpenters Joint Apprenticeship Committee, 2566 12th Avenue, Vero Beach Florida, 32960, should be discountinued, as provided in 38 CFR 21.4134, because a requirement of law is not being met or a provision of the law has been violated. All interested persons shall be permitted to attend, appear before, or file statements with the Committee at that time and place.

Dated: November 1, 1982.

Carlos L. Rainwater,

Director.

[FR Doc. 82-30806 Filed 11-8-82; 8:45 am]

BILLING CODE 8320-01-M

Sunshine Act Meetings

Federal Register
Vol. 47, No. 217
Tuesday, November 9, 1982

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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1

CONSUMER PRODUCT SAFETY COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCMENT: 47 FR 49787.

PREVIOUSLY ANNOUNCED TIME AND DATE: 10 a.m., November 3, 1982.

CHANGES IN THE MEETING: Meeting cancelled. Compliance Status Report rescheduled for November 10, 1982. For a recorded message on the latest Agenda information call (301) 492-5707.

[S-1621-82 Filed 11-5-82; 12:50 pm]

BILLING CODE 6355-01-M

2

DEPOSITORY INSTITUTIONS DEREGULATION COMMITTEE

TIME AND DATE: 8 a.m., November 15, 1982

PLACE: Cash Room, Department of the Treasury (use Pennsylvania Avenue Entrance) Pennsylvania Avenue between 15th Street and East Executive Avenue, Washington, D.C. 20220.

STATUS: Open. Matters to be considered:

1. The features of the new money market deposit account mandated by the Garn-St Germain Depository Institutions Act of 1982.

Note.—The meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the DIDC Offices at the Department of the Treasury, and copies may be purchased for $5.00 a cassette by calling (202) 566-5152 or by writing to: Depository Institutions Deregulation Committee, Department of the Treasury, Room 1058 MT, Washington, D.C. 20220.

For further information about the DIDC and the November 15 meeting please call (202) 566-3734.

November 5, 1982.

Gordon Eastburn,

Acting Executive Secretary of the Committee.

[S-1618-82 Filed 11-5-82; 11:00 am]

BILLING CODE 6210-01-M

3

FEDERAL COMMUNICATIONS COMMISSION

November 3, 1982.

Deletion of Agenda Item From November 4th Open Meeting

The following item has been deleted at the request of the Office of Commissioner Quello from the list of agenda items scheduled for consideration at the November 4, 1982 Open Meeting, and previously listed in the Commission's Notice of October 28, 1982.

Agenda, Item No., and Subject

General—2—*Title:* UHF Television Receiver Noise Figures. *Summary:* The Commission will consider whether to adopt a *Notice of Proposed Rulemaking* in Docket 21010, proposing to reduce the maximum allowable UHF television receiver noise figure to 12 dB, and to make associated rule changes.

Issued: November 3, 1982.

William J. Tricarico,

Secretary, Federal Communications Commission.

[S-1618-82 Filed 11-5-82; 11:20 am]

BILLING CODE 6712-01-M

4

FEDERAL COMMUNICATIONS COMMISSION

FCC Holds Emergency Closed Meeting, Thursday, November 4th

The Federal Communications Commission held an Emergency Closed Meeting on Thursday, November 4, 1982, at 1919 M Street, NW., Washington, D.C. on litigation strategy relating to the decision in the matter listed below:

Agenda, Item No., and Subject

Broadcast—1—Title: Applications for interim Direct Broadcast Satellite (DBS) systems filed by CBS, Inc., Direct Broadcast Satellite Company, Focus Broadcast Satellite Company, Graphic Scanning Corporation, RCA American Communications, Inc., United States Satellite Broadcasting Company, Inc., Video Satellite Systems, Inc., and Western Union Telegraph Company and associated petitions to deny, comments, and other responsive pleadings. Summary: The above referenced applicants seek authority to establish interim Direct Broadcast Satellite (DBS) systems. These applications are subject to petitions to deny, comments, and other responsive pleadings.

The prompt and orderly conduct of Commission business did not permit announcment of this matter prior to the meeting.

This meeting was closed to the public because it concerned adjudicatory matters (See 47 CFR 0.603 (j)).

The following persons attended this meeting:

Commissioners and their Assistants
General Counsel and members of his staff
Managing Director and members of his staff
Chief, Broadcast Bureau and members of his staff
Chief, Office of Public Affairs and members of his staff

Actions by the Commission November 4, 1982. Commissioners Fowler, Chairman; Quello, Fogarty, Jones, Dawson and Sharp voting to consider this matter in Closed Session.

Additional information concerning this matter may be obtained from Maureen Peratino, FCC Public Affairs Office, telephone number (202) 254-7674.

William J. Tricarico,

Secretary, Federal Communications Commission.

[S-1619-82 Filed 11-5-82; 11:25 am]

BILLING CODE 6712-01-M

5

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 10:35 a.m. on Wednesday, November 3, 1982, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session, by telephone conference call, to (1) receive bids for the purchase of certain assets of and the assumption of the liability to pay deposits made in Cedar Bluff Bank, Cedar Bluff, Alabama, which was placed in voluntary liquidation by its board of directors and closed on Tuesday, November 2, 1982; (2) accept the bid for the transaction submitted by Union State bank, Cedar Bluff, Alabama; (3) approve the applications of Union State Bank, Cedar Bluff, Alabama, for Federal deposit insurance, and for consent to purchase certain

assets of and to assume the liability to pay deposits made in Cedar Bluff Bank, Cedar Bluff, Alabama; and (4) provide such financial assistance, pursuant to section 13(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)(2)), as was necessary to effect the purchase and assumption transaction.

At that same meeting, the Board of Directors considered an aplication for financial assistance, pursuant to section 13(c) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)), by an insured bank. The name and location of the bank are authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), and (c)(9)(A)(ii)).

In calling the meeting, the Board determined, on motion of Chariman William M. Isaac, seconded by Director Irvine H. Sprague (Appointive), concurred in by Director C. T. Conover (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(6), (c)(8), (c)(9)(A)(ii), and (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: November 4, 1982.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-1617-82 File 11-5-82; 11:19 am]

BILLING CODE 6714-01-M

6

FEDERAL ELECTION COMMISSION

[FR No. 1596]

PREVIOUSLY ANNOUNCED DATE AND TIME: Wednesday, November 10, 1982 at 11 a.m.

CHANGE IN MEETING: The following matter has been *deleted* for the meeting of this date:

Proposed regulations on joint fundraising and collecting agents (11 CFR 102.6 and 102.7)

The following matter has been *added* for the meeting of this date:

Proposed revision of 11 CFR 114.3 and 114.4

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Public Information Officer.

Marjorie W. Emmons,

Secretary of the Commission.

[S-1620-82 Filed 11-5-82; 12:17 pm]

BILLING CODE 6717-01-M

7

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

November 3, 1982.

TIME AND DATE: 10 a.m., Wednesday, November 10, 1982.

PLACE: Room 600, 1730 K Street, N.W., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will hear oral argument on the following:

1. Florence Mining Company, Docket No. PITT 77-15, etc., IBMA 77-32. (The Commissioners granted the operators' petition for reconsideration of the Commission's August 31, 1982 decision, and the issues include whether 30 CFR 75.1405 applies to certain mine haulage equipment.)

* * * * *

TIME AND DATE: 11 a.m., or following oral argument, Wednesday, November 10, 1982.

PLACE: Same as above.

STATUS: Closed (Pursuant to 5 U.S.C. 552(c)(10)).

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

2. Florence Mining Company—same as above.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653-5632.

[S-1626-82 Filed 11-5-82; 3:13 pm]

BILLING CODE 6735-01-M

8

FEDERAL RESERVE SYSTEM

(Board of Governors)

TIME AND DATE: 10 a.m., Monday, November 15, 1982.

PLACE: 20th Street and Constitution Avenue, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board, (202) 452-3204.

Dated: November 5, 1982.

James McAfee,

Associate Secretary of the Board.

[S-1624-82 Filed 11-5-82; 3:13 pm]

BILLING CODE 6210-01-M

9

INTERNATIONAL TRADE COMMISSION

Executive Resources Board (ERB)

[USITC ERB-82-3A]

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 47 FR 49919, NOVEMBER 3, 1982.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 11 a.m., Monday, November 15, 1982.

CHANGES IN THE MEETING: The Executive Resources Board (ERB) of the United States International Trade Commission has rescheduled the ERB meeting for Monday, November 15, 1982, at 10:00 a.m., instead of 11:00 a.m. There are no other changes to the agenda.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523-0161.

[S-1622-82 Filed 11-5-82; 2:10 pm]

BILLING CODE 7020-02-M

10

[USITC SE-82-49]

TIME AND DATE: 10 a.m., Friday, November 19, 1982.

PLACE: Room 117, 701 E. Street, N.W., Washington, D.C. 20436.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

1. Investigation 701-TA-200 [Preliminary] (Automated Fare Card Collection Equipment and Parts Thereof from France)—briefing and vote.

CONTACT PERSON FOR MORE INFORMATION: Kenneth R. Mason, Secretary (202) 523-0161.

[S-1623-82 Filed 11-5-82; 2:10 pm]

BILLING CODE 7020-02-M

11

PAROLE COMMISSION

[3P0401]

National Commissioners (the Commissioners presently maintaining offices at Chevy Chase, Maryland Headquarters).

TIME AND DATE: 10 a.m., Tuesday, November 9, 1982.

PLACE: Room 420–F, One North Park Building, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815.

STATUS: Closed meeting to a vote to be taken at the beginning of the meeting.

MATTERS TO BE CONSIDERED: Referrals from Regional Commissioners of approximately 5 cases in which inmates of Federal prisons have applied for parole or are contesting revocation of parole or mandatory release.

CONTACT PERSON FOR MORE INFORMATION: Linda Wines Marble, Chief Case Analyst, National Appeals Board, United States Parole Commission, (301) 492–5987.

[S–1625–82 Filed 11–5–82; 3:13 pm]

BILLING CODE 4410–01–M

federal register

Tuesday
November 9, 1982

Part II

Department of Health and Human Services

Food and Drug Administration

Immunology and Microbiology Devices; General Provisions and Classification of 162 Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 78N-2113]

Immunology and Microbiology Devices; General Provisions and Classification of 162 Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying 162 immunology and microbiology devices in commercial distribution. The preamble to this rule responds to comments received on the proposals regarding classification of these devices. This action is being taken under the Medical Device Amendments of 1976.

EFFECTIVE DATE: December 9, 1982.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi (Immunology), Thomas M. Tsakeris (Microbiology), National Center for Devices and Radiological Health (HFK-440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 22, 1980 (45 FR 27204-27359), FDA published proposed regulations containing general provisions applicable to the classification of immunology and microbiology devices and individual proposed regulations to classify 160 immunology and microbiology devices into one or more of three regulatory classes: class I (general controls), class II (performance standards), and class III (premarket approval). Of the 160 immunology and microbiology devices that were the subject of proposals, FDA is classifying 93 devices into class I (general controls), 64 devices into class II (performance standards), and two devices into class III (premarket approval). One proposed classification is being withdrawn, because the product is a licensed biologic and is regulated by FDA's National Center for Drugs and Biologics (hemolytic immunological test system, Docket No. 78N-2253, **Federal Register** of March 19, 1982; 47 FR 11880). FDA has decided not to publish classification regulations on medical devices that also are licensed biologics under section 351 of the Public Health Service Act (42 U.S.C. 262). Additionally, FDA is codifying the statute's classification into class III of 3 transitional immunology and microbiology devices previously considered new drugs that are in commercial distribution. Proposed regulations on these statutory classifications were unnecessary.

Classification of medical devices in commercial distribution is required by the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301-392). The effect of classifying a device into class I is to require that the device continue to meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application that includes information concerning safety and effectiveness tests for the device. For a class III device not considered a new drug before the amendments that either was in commercial distribution before May 28, 1976, or is substantially equivalent to a device that was in commercial distribution before that date, each application for premarket approval must be submitted to FDA on or before June 28, 1985, or 90 days after promulgation of a separate regulation requiring premarket approval of the device, whichever occurs later. For a class III device previously considered a new drug, the requirement of having premarket approval is already in effect. See section 520(1) of the act (21 U.S.C. 360j(1)).

The preamble to the proposed general provisions described the development of the general provisions and the proposed regulations classifying immunology and microbiology devices and the activities of the Immunology and Microbiology Devices Panel (formerly the Immunology Device Classification Panel and the Microbiology Device Classification Panel), an FDA advisory committee that makes recommendations to FDA concerning the classification of immunology and microbiology devices. FDA provided a period of 60 days for interested persons to submit written comments on these proposals. The comments received are discussed below.

Change in Format of Final Rules for Classification of Devices

To reduce printing costs, FDA is publishing as one final regulation the general provisions and classifications of 162 immunology and microbiology devices. Formerly, a separate final classification regulation was published in the **Federal Register** for each generic type of device. The docket number used to identify each of the proposed classification regulations continues to be used in this final regulation to identify each generic type of device.

Exemptions for Class I Devices

FDA proposed to exempt seven generic types of immunology and microbiology devices from requirements of the premarket notification procedures in Subpart E of Part 807 (21 CFR Part 807): Complement reagent (Docket No. 78N-2212), radial immunodiffusion plate (Docket No. 78N-2217), anaerobic chamber (Docket No. 78N-2119), manual colony counter (Docket No. 78N-2123); automated media dispensing and stacking device (Docket No. 78N-2131); microbiological incubator (Docket No. 78N-2135); and Wood's fluorescent lamp (Docket No. 78N-2138). The final rule for each of the seven devices exempts the device from the requirements of the premarket notification procedures. Further, FDA proposed to exempt each of the latter five of these seven devices from all of the requirements of the good manufacturing practice (GMP) regulations in Part 820 (21 CFR Part 820) with the exception of §§ 820.180 and 820.198 relating to records and complaint files. This final regulation exempts each of the latter five of the above devices from most requirements of the GMP regulations. FDA did not receive any public comments on the seven proposals.

The agency has determined that exemption of any device from requirements of §§ 820.180 and 820.198 of the GMP regulations would not be in the public interest. Moreover, compliance with these sections is not unduly burdensome for device manufacturers. The complaint file requirements of § 820.198 ensure that device manufacturers have adequate systems for complaint investigation and followup. The general requirements concerning records in § 820.180 ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, can determine whether the manufacturer's corrective actions are adequate, and can determine whether an exemption from other sections of the GMP regulation, if one has been granted, is still appropriate. Also, for the reasons given in the proposal, these exemptions do not apply to devices that are labeled or otherwise represented as sterile.

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions

of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** on Friday, January 18, 1980 (45 FR 3671).

Devices That Have Both Medical and Nonmedical Uses

FDA has clarified several regulations classifying products that have both medical and nonmedical uses. FDA will regulate a multipurpose product as a medical device if it is intended for a medical purpose, i.e., for "use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease," or "to affect the structure or any function of the body." (Section 201(h) of the act (21 U.S.C. 321(h)).) FDA will determine the intended use of a product based upon the expressions of the person legally responsible for its labeling and by the circumstances surrounding its distribution. The most important factors the agency will consider in determining the intended use of a particular product are the labeling, advertising, and other representations accompanying the product. Products that have medical uses only are clearly intended for medical purposes and, therefore, will be regulated as medical devices whether or not medical claims are made for them.

Changes in Classification in Final Regulations

Based on the comments received or upon reconsideration, FDA has changed the classification of each of six devices in the final regulations from that originally proposed. The classification of four devices was changed from class I to class II: cytomegalovirus serological reagents (Docket No.78N-2157), *Haemophilus* spp. serological reagents (Docket No. 78N-2169). varicella-zoster virus serological reagents (Docket No. 78N-2210), and total spinal fluid immunological test systems (Docket No. 78N-2278). The classification for two devices was changed from class II to class III: herpes simplex virus serological reagents (Docket No. 78N-2170) and rubella virus serological reagents (Docket No. 78N-2192). The reasons for these changes are identified in the discussion under each of these six docket numbers. FDA does not believe that it is necessary to issue a new proposal concerning these changes. The purpose of publishing a proposal and soliciting comments is to enable the agency to determine whether its proposed classification of a device is correct. After reviewing the comments submitted on a proposal or after reconsideration, the agency may determine that its proposed classification is incorrect. Persons interested in the classification process should therefore anticipate that in a final regulation a device may be placed in a class different from the one originally proposed. This possibility was specifically identified in the proposed general provisions for immunology and microbiology devices (see 45 FR 27204; April 22, 1980). Persons who disagree with a final classification for a device may petition for reclassification of the device under Subpart C of Part 860 (21 CFR Part 860). Occasionally the agency has made minor changes in device names or identifications to clarify the final regulations. Additionally, the agency is adding an explanation in § 866.1 that references in Part 866 to other regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

Changes in Device Advisory Committee Names

On April 28, 1978, the agency terminated all of the device classification panels, then reestablished them under new names and with a new structure. FDA published notices of these changes in the **Federal Register** of May 19, 1978 (43 FR 21666, 21667, and 21668) and May 26, 1978 (43 FR 22672 and 22673). The Immunology Device Classification Panel and the Microbiology Device Classification Panel were terminated, and their functions are now conducted by the Immunology Device Section and the Microbiology Device Section of the Immunology and Microbiology Devices Panel. Further, in the **Federal Register** of September 3, 1982 (47 FR 38883), FDA announced the establishment on August 5, 1982, of the Obstetrics-Gynecology Devices Panel and the Radiologic Devices Panel and the termination of the Obstetrics-Gynecology and Radiologic Devices Panel.

Classification Regulations Published to Date

The following table shows the current structure of the advisory committees involved with the classification of medical devices and a list of all proposed and final classification regulations published to date:

Panel/section name	Publication date in FEDERAL REGISTER
Circulatory Systems Devices Panel.	
Mar. 9, 1979, 44 FR 13284-13434 (proposals); Feb. 5, 1980, 45 FR 7904-7971 (final regulations).	
Clinical Chemistry and Hematology Devices Panel	
Clinical Chemistry Device Section.	Feb. 2, 1982, 47 FR 4802-4929 (proposals).
Clinical Toxicology Device Section.	Feb. 2, 1982, 47 FR 4802-4929 (proposals).
Hematology and Pathology Device Section.	Sept. 11, 1979, 44 FR 53063 (proposals); Sept. 12, 1980, 45 FR 60576-60651 (final regulations).
General Medical Devices Panel	
General Hospital and Personal Use Device Section.	Aug. 24, 1979, 44 FR 49844-49954 (proposals); Oct. 21, 1980, 45 FR 69678-69737 (final regulations).
Gastroenterology-Urology Device Section.	Jan. 23, 1981, 46 FR 7562-7641 (proposals).
Immunology and Microbiology Devices Panel	
Immunology Device Section.	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982 (final regulations.)
Microbiology Device Section.	Apr. 22, 1980, 45 FR 27204-27359 (proposals); Nov. 9, 1982. (final regulations).
Obstetrics-Gynecology Devices Panel.	Apr. 3, 1979, 44 FR 19894-19971 (proposals); Feb. 26, 1980, 45 FR 12682-12720 (final regulations).
Radiologic Devices Panel	Jan. 29, 1982, 47 FR 4406-4451 (proposals).
Ophthalmic; Ear, Nose, and Throat; and Dental Devices Panel	
Ophthalmic Device Section.	Jan. 26, 1982, 47 FR 3694-3749, (proposals).
Ear, Nose, and Throat Device Section.	Jan. 22, 1982, 47 FR 3280-3325 (proposals).
Dental Device Section	Dec. 30, 1980, 45 FR 85962-86168 (proposals).
Respiratory and Nervous System Devices Panel	
Anesthesiology Device Section.	Nov. 2, 1979, 44 FR 63292-63426 (proposals); July 16, 1982, 47 FR 31130-31150 (final regulations).
Neurological Device Section.	Nov. 23, 1978, 43 FR 54640-55732 (proposals); Sept. 4, 1979, 44 FR 51726-51778 (final regulations).
Surgical and Rehabilitation Devices Panel	
Physical Medicine Device Section.	Aug. 28, 1979, 44 FR 50458-50537 (proposals).
Orthopedic Device Section.	July 2, 1982, 47 FR 29052-29140 (proposals).
General and Plastic Surgery Device Section.	Jan. 19, 1982, 47 FR 2810-2853 (proposals).

Transitional Devices

The amendments included transitional provisions applicable to devices intended for human use that were declared to be new drugs or antibiotic drugs before enactment of the amendments. (See section 520(l)(1)(E) of the act (21 U.S.C. 360j(l)(1)(E).) The transitional provisions assure that devices formerly regarded as new drugs or antibiotic drugs continue to be subject to needed regulatory controls as the amendments are being implemented. A device previously considered a new drug is classified into class III unless the agency in response to a petition has reclassified it into class I or class II. FDA is including in this final rule

provisions to codify the statutory classification into class III of the following 3 commercially distributed, transitional immunology and microbiology devices, which were the subject of the **Federal Register** notices on their former status as new drugs as listed below:

Device	Section; docket	Relevant notices
1. Oxidase screening test for gonorrhea	866.2420; 81N-0103	39 FR 3705; Jan. 29, 1974; 42 FR 63471; Dec. 16, 1977.
2. Gonococcal antibody test (GAT)	866.3290; 81N-0104	39 FR 3705; Jan. 29, 1974; 42 FR 63471; Dec. 16, 1977; 46 FR 28946; May 29, 1981.
3. Carcinoembryonic antigen (CEA) immunological test system as an aid in the detection and management of cancer.	866.6010; 81N-0102	38 FR 10488; Apr. 27, 1973; 45 FR 58964; Sept. 5, 1980.

There are, in addition, three other transitional immunological devices that are investigational and that are not in commercial distribution. Accordingly, these devices are not being made the subject of device classification regulations. These three devices are the alpha-1-fetoprotein, the Tennessee antigen, and the tissue polypeptide antigen immunological test systems when each is used as an aid in the detection and management of cancer.

Relevant notices were published in the **Federal Register** of April 27, 1973 (38 FR 10488) and September 5, 1980 (45 FR 58964). If FDA approves a premarket approval application for an investigational transitional device, the agency will publish a final classification regulation describing the device's statutory classification into class III.

As explained above, class III transitional devices that were previously considered new drugs are subject now to premarket approval.

Orders Issued in Response to Reclassification Petitions on Immunology Devices

In addition to classifying commercially marketed preamendments devices and issuing regulations describing the statutory classification of transitional devices, FDA also announces its decisions on reclassification petitions for devices first marketed after the enactment date of the amendments. Postamendments devices that are not substantially equivalent to devices marketed before the amendments are classified by statute into class III by action of section 513(f)(1) of the act without FDA rulemaking. In response to a petition received by FDA under section 513(f)(2) of the act and 21 CFR Part 860 of the regulations, FDA may reclassify a new device into class I or class II. The agency has received two such petitions concerning immunology devices. FDA is announcing the agency's decisions on the petitions. FDA also is issuing final regulations that describe the agency's reclassification of the devices that were subject of the petitions.

Petition 77P-0337; § 866.5240; Docket No. 78N-2235; Complement components immunological test system.

On June 28, 1977, FDA received petition 77P-0337 under section 513(f) of the act requesting that the agency reclassify the petitioner's "FIAX™ test kit for C3" from class III to class II. In the **Federal Register** (43 FR 5071) of February 7, 1978, FDA published the recommendation of the Immunology Device Section of the Immunology and Microbiology Devices Panel that the device be reclassified from class III to class II. The agency provided a period of 30 days for interested persons to submit written comments on the recommendation. No comments were received. FDA agreed with the panel's recommendation that the device be reclassified. In accordance with section 513(f)(2)(C)(i) of the act and 21 CFR 860.134(b)(6) of the regulations, FDA approved the petition and, by order in the form of a letter dated March 24, 1978 and sent to the petitioner, reclassified the device from class III to class II. Based upon additional findings of the panel, FDA advises that the device should be used in conjunction with other methods of diagnosis, such as observation of symptoms and examination of the patient's medical history.

FDA advises that the test kit for C3 reclassified into class II in response to the petition is included in the generic type of device in this final rule identified in § 866.5240 Complement components immunological test system (Docket No. 78N-2235). Accordingly, FDA announces the agency's decision on reclassification petition 77P-0337 as provided in 21 CFR 860.134(b)(7).

Petition 77P-0339; § 866.5100; Docket No. 78N-2225; Anti-nuclear antibody immunological test system.

On July 18, 1977, FDA received petition 77P-0339 under section 513(f) of the act requesting that the agency reclassify the petitioner's "FIAX ™ anti-DNA antibody test" from class III to class II. In the **Federal Register** of February 3, 1978 (43 FR 4680), FDA published the recommendation of the Immunology Device Section of the Immunology and Microbiology Devices Panel that the device be reclassified from class III to class II. The agency provided a period of 30 days for interested persons to submit written comments on the recommendation. The one comment received stated that the data used to support the petitioner's claim that its device was substantially equivalent to another manufacturer's commercially marketed preamendments anti-DNA antibody test kit shows that the petitioner's results were expressed in percent binding, while the preamendments device's results were reported in units of anti-DNA binding activity per milliliter. The comment said that because of the difference in the method used to report the test results from the petitioner's device, the petitioner had not demonstrated its device was substantially equivalent to the commercially marketed preamendments device.

FDA partially agrees with the comment. FDA agrees that the petitioner modified the method of reporting test results. However, FDA believes that the data submitted by the petitioner provided ample evidence that its device can discriminate between the disease and non-disease population and that this minor alteration does not significantly affect the clinical equivalence of its test results when compared with the results obtained using the preamendments device. Thus, FDA agreed with the panel's recommendation that the device be reclassified.

In accordance with section 513(f)(2)(C)(i) of the act and 21 CFR 860.134(b)(6) of the regulations, FDA approved the petition and, by order in the form of a letter dated April 12, 1978, and sent to the petitioner, reclassified the device from class III to class II. Based upon additional findings of the panel, FDA advises that the device should be used in conjunction with other methods of diagnosis, such as observation of symptoms, and examination of the patient's medical history.

FDA advises that the anti-DNA antibody test system reclassified into class II in response to the petition is included in the generic type of device in this final rule identified in § 866.5100 Anti-nuclear antibody immunological test system (Docket No. 78N-2225).

Accordingly, FDA announces the agency's decision on reclassification petition 77P–0339 as provided in 21 CFR 860.134(b)(7).

Related Regulations

In the **Federal Register** of September 7, 1982 (47 FR 39155), FDA amended the antibiotic drug and new animal drug regulations to exempt all classes of antibiotic drugs and antibiotic susceptibility devices from batch certification requirements. Certain devices identified in this final regulation to classify immunology and microbiology devices are antibiotic susceptibility devices: § 866.1620 Antimicrobial susceptibility test disc (Docket No. 78N–2114) and § 866.1640 Antimicrobial susceptibility test powder (Docket No. 78N–2115).

In a final report submitted to FDA by the Panel on Review of Blood and Blood Derivatives, the advisory panel questioned the value of the serological test for syphilis as a routine screening test for potential blood donors. The serological test for syphilis is included in the generic type of device identified in § 866.3820 *Treponema pallidum* nontreponemal test reagents. In the **Federal Register** of November 21, 1980 (45 FR 77134), FDA announced the availability of that panel report.

List of Immunology and Microbiology Devices and an Identification of Those Proposed Classification Regulations That Received Public Comments

The following is a list of immunology and microbiology devices being classified in this final regulation. The list shows the section of the Code of Federal Regulations under which the device classification is being codified, the docket number of the proposed classification regulation, the classification of each device, and a statement (yes or no) whether public comments were received on the proposed classification regulation. If no comments were received, the device is being classified as proposed.

Section	Device	Docket No.	Class	Comments
	Subpart B.—Diagnostic Devices			
866.1620	Antimicrobial susceptibility test disc	78N–2114	II	Yes.
866.1640	Antimicrobial susceptibility test powder	78N–2115	II	Yes.
866.1700	Culture medium for antimicrobial susceptibility tests	78N–2117	II	No.
	Subpart C—Microbiology Devices			
866.2050	Staphylococcal typing bacteriophage	78N–2118	I	Yes.
866.2120	Anaerobic chamber	78N–2119	I	No.
866.2160	Coagulase plasma	78N–2121	II	No.
866.2170	Automated colony counter	78N–2122	I	No
866.2180	Manual colony counter	78N–2123	I	No.
866.2300	Multipurpose culture medium	78N–2124	I	Yes.
866.2320	Differential culture medium	78N–2125	I	Yes.
866.2330	Enriched culture medium	78N–2126	I	Yes.
866.2350	Microbiological assay culture medium	78N–2127	I	Yes.
866.2360	Selective culture medium	78N–2128	I	Yes.
866.2390	Transport culture medium	78N–2129	I	Yes.
866.2410	Culture medium for pathogenic *Neisseria* spp.	78N–2130	II	No.
866.2420	Oxidase screening test for gonorrhea	81N–0103	III	(1)
866.2440	Automated medium dispensing and stacking device	78N–2131	I	No.
866.2450	Supplement for culture media	78N–2132	I	Yes.
866.2480	Quality control kit for culture media	78N–2133	I	Yes.
866.2500	Microtiter diluting and dispensing device	78N–2134	I	No.
866.2540	Microbiological incubator	78N–2135	I	No.
866.2560	Microbial growth monitor	78N–2136	I	No.
866.2580	Gas-generating device	78N–2137	I	No.
866.2600	Wood's fluorescent lamp	78N–2138	I	No.
866.2660	Microorganism differentiation and identification device	78N–2139	I	No.
866.2850	Automated zone reader	78N–2140	I	No.
866.2900	Microbiological specimen collection and transport device	78N–2141	I	No.
	Subpart D—Serological Reagents			
866.3010	*Acinetobacter calcoaceticus* serological reagents	78N–2281	I	No.
866.3020	Adenovirus serological reagents	78N–2142	I	No.
866.3035	*Arizona* spp. serological reagents	78N–2143	I	Yes.
866.3040	*Aspergillus* spp. serological reagents	78N–2144	I	Yes.
866.3060	*Blastomyces dermatitidis* serological reagents	78N–2145	II	No.
866.3065	*Bordetella* spp. serological reagents	78N–2146	I	No.
866.3085	*Brucella* spp. serological reagents	78N–2147	II	No.
866.3110	*Campylobacter fetus* serological reagents	78N–2149	I	Yes.
866.3120	Chlamydia serological reagents	78N–2150	I	No.
866.3125	*Citrobacter* spp. serological reagents	78N–2151	I	No.
866.3135	*Coccidioides immitis* serological reagents	78N–2152	II	No.
866.3140	*Corynebacterium* spp. serological reagents	78N–2153	I	Yes.
866.3145	Coxsackievirus serological reagents	78N–2154	I	No.
866.3165	*Cryptococcus neoformans* serological reagents	78N–2156	II	Yes.
866.3175	Cytomegalovirus serological reagents	78N–2157	II	Yes.
866.3200	*Echinococcus* spp. serological reagents	78N–2158	I	No.
866.3205	Echovirus serological reagents	78N–2159	I	No.
866.3220	*Entamoeba histolytica* serological reagents	78N–2160	II	No.
866.3235	Epstein-Barr Virus Serological reagents	78N–2162	I	No.
866.3240	Equine encephalomyelitis virus serological reagents	78N–2163	I	No.
866.3250	*Erysipelothrix rhusiopathiae* serological reagents	78N–2164	I	No.
866.3255	*Escherichia coli* serological reagents	78N–2165	I	No.
866.3270	*Flavobacterium* spp. serological reagents	78N–2166	I	No.
866.3280	*Francisella tularensis* serological reagents	78N–2167	II	No.
866.3290	Gonococcal antibody test (GAT)	81N–0103	III	(1)
866.3300	*Haemophilus* spp. serological reagents	78N–2169	II	Yes.
866.3305	Herpes simplex virus serological reagents	78N–2170	III	Yes.
866.3320	*Histoplasma capsulatum* serological reagents	78N–2173	II	No.
866.3330	Influenza virus serological reagents	78N–2174	I	No.
866.3340	*Klebsiella* spp. serological reagents	78N–2175	I	No.
866.3350	*Leptospira* spp. serological reagents	78N–2176	II	No.

Section	Device	Docket No.	Class	Comments
866.3355	*Listeria* spp. serological reagents	78N-2177	I	No.
866.3360	Lymphocytic choriomeningitis virus serological reagents	78N-2178	I	No.
866.3370	*Mycobacterium tuberculosis* immunofluorescent reagents	78N-2179	I	No.
866.3375	*Mycoplasma* spp. serological reagents	78N-2180	I	No.
866.3380	Mumps virus serological reagents	78N-2181	I	No.
866.3390	*Neisseria* spp. direct serological test reagents	78N-2182	II	No.
866.3400	Parainfluenza virus serological reagents	78N-2183	I	No.
866.3405	Poliovirus serological reagents	78N-2184	I	No.
866.3410	*Proteus* spp. (Weil-Felix) serological reagents	78N-2185	I	No.
866.3415	*Pseudomonas* spp. serological reagents	78N-2186	II	No.
866.3460	Rabiesvirus immunofluorescent reagents	78N-2187	II	No.
866.3470	Reovirus serological reagents	78N-2188	I	No.
866.3480	Respiratory syncytial virus serological reagents	78N-2189	I	No.
866.3490	Rhinovirus serological reagents	78N-2190	I	No.
866.3500	Rickettsia serological reagents	78N-2191	I	No.
866.3510	Rubella virus serological reagents	78N-2192	III	Yes.
866.3520	Rubeola (measles) virus serological reagents	78N-2193	I	No.
866.3550	*Salmonella* spp. serological reagents	78N-2194	II	No.
866.3600	*Schistosoma* spp. serological reagents	78N-2197	I	No.
866.3630	*Serratia* spp. serological reagents	78N-2198	I	No.
866.3660	*Shigella* spp. serological reagents	78N-2199	II	No.
866.3680	*Sporothrix schenckii* serological reagents	78N-2200	I	No.
866.3700	*Staphylococcus aureus* serological reagents	78N-2201	I	No.
866.3720	*Streptococcus* spp. exoenzyme reagents	78N-2202	II	Yes.
866.3740	*Streptococcus* spp. serological reagents	78N-2203	I	Yes.
866.3780	*Toxoplasma gondii* serological reagents	78N-2204	II	Yes.
866.3820	*Treponema pallidum* nontreponemal test reagents	78N-2206	II	No.
866.3830	*Treponema pallidum* treponemal test reagents	78N-2207	II	No.
866.3850	*Trichinella spiralis serological reagents*	78N-2208	I	No.
866.3870	*Trypanosoma* spp. serological reagents	78N-2209	I	No.
866.3900	Varicella-zoster virus serological reagents	78N-2210	II	Yes.
866.3930	*Vibrio cholerae* serological reagents	78N-2211	II	No.
	Subpart E.—Immunology Laboratory Equipment and Reagents			
866.4100	Complement reagent	78N-2212	I	No.
866.4500	Immunoelectrophoresis equipment	78N-2213	I	No.
866.4520	Immunofluorometer equipment	78N-2214	I	No.
866.4540	Immunonephelometer equipment	78N-2215	I	No.
866.4600	Ouchterlony agar plate	78N-2216	I	No.
866.4800	Radial immunodiffusion plate	78N-2217	I	No.
866.4830	Rocket immunoelectrophoresis equipment	78N-2218	I	No.
866.4900	Support gel	78N-2219	I	No.
	Subpart F.—Immunological Test Systems			
866.5040	Albumin immunological test system	78N-2220	II	No.
866.5060	Prealbumin immunological test system	78N-2221	I	No.
866.5065	Human allotypic marker immunological test system	78N-2222	I	Yes.
866.5080	*Alpha*-1-antichymotrypsin immunological test system	78N-2223	II	No.
866.5090	Antimitochondrial antibody immunological test system	78N-2224	II	No.
866.5100	Antinuclear antibody immunological test system	78N-2225	II	No.
866.5110	Antiparietal antibody immunological test system	78N-2226	II	No.
866.5120	Antismooth muscle antibody immunological test system	78N-2227	II	No.
866.5130	*Alpha*-1-antitrypsin immunological test system	78N-2228	II	No.
866.5150	Bence-Jones proteins immunological test system	78N-2229	II	No.
866.5160	*Beta*-globulin immunological test system	78N-2284	I	No.
866.5170	Breast milk immunological test system	78N-2230	I	No.
866.5200	Carbonic anhydrase B and C immunological test system	78N-2231	I	No.
866.5210	Ceruloplasmin immunological test system	78N-2232	II	No.
866.5220	Cohn fraction II immunological test system	78N-2233	I	No.
866.5230	Colostrum immunological test system	78N-2234	I	No.
866.5240	Complement components immunological test system	78N-2235	II	No.
866.5250	Complement C_1 inhibitor (inactivator) immunological test system	78N-2236	II	No.
866.5260	Complement C_{3b} inactivator immunological test system	78N-2237	II	No.
866.5270	C-reactive protein immunological test system	78N-2238	II	Yes.
866.5320	Properdin factor B immunological test system	78N-2239	II	No.
866.5330	Factor XIII, A, S, immunological test system	78N-2240	I	No.
866.5340	Ferritin immunological test system	78N-2241	II	No.
866.5350	Fibrinopeptide A immunological test system	78N-2242	II	No.
866.5360	Cohn fraction IV immunological test system	78N-2243	I	No.
866.5370	Cohn fraction V immunological test system	78N-2244	I	No.
866.5380	Free secretory component immunological test system	78N-2245	II	No.
866.5400	*Alpha*-globulin immunological test system	78N-2246	I	No.
866.5420	*Alpha*-1-glycoproteins immunological test system	78N-2247	I	No.
866.5425	*Alpha*-2-glycoproteins immunological test system	78N-2248	I	No.
866.5430	*Beta*-2-glycoprotein I immunological test system	78N-2249	I	No.
866.5440	*Beta*-2-glycoprotein III immunological test system	78N-2250	I	No.
866.5460	Haptoglobin immunological test system	78N-2251	II	No.
866.5470	Hemoglobin immunological test system	78N-2252	II	No.
866.5490	Hemopexin immunological test system	78N-2254	II	No.
866.5500	Hypersensitivity pneumonitis immunological test system	78N-2255	II	No.
866.5510	Immunoglobulins A, G, M, D, and E immunological test system	78N-2256	II	No.
866.5520	Immunoglobulin G (Fab fragment specific) immunological test system	78N-2257	II	Yes.
866.5530	Immunoglobulin G (Fc fragment specific) immunological test system	78N-2258	II	No.
866.5540	Immunoglobulin G (Fd fragment specific) immunological test system	78N-2283	I	No.
866.5550	Immunoglobulin (light chain specific) immunological test system	78N-2259	II	No.
866.5560	Lactic dehydrogenase immunological test system	78N-2260	I	No.
866.5570	Lactoferrin immunological test system	78N-2261	I	No.
866.5580	*Alpha*-1-lipoprotein immunological test system	78N-2262	II	No.
862.5590	Lipoprotein X immunological test system	78N-2263	I	No.
862.5600	Low-density lipoprotein immunological test system	78N-2264	II	No.
866.5620	*Alpha*-2-macroglobulin immunological test system	78N-2265	II	No.
866.5630	*Beta*-2-microglobulin immunological test system	78N-2266	II	No.

Section	Device	Docket No.	Class	Comments
866.5640	Infectious mononucleosis immunological test system	78N-2267	II	No.
866.5660	Multiple autoantibodies immunological test system	78N-2268	II	No.
866.5680	Myoglobin immunological test system	78N-2269	II	No.
866.5700	Whole human plasma or serum immunological test system	78N-2270	I	No.
866.5715	Plasminogen immunological test system	78N-2271	I	No.
866.5735	Prothrombin immunological test system	78N-2272	I	No.
866.5750	Radioallergosorbent (RAST) immunological test system	78N-2273	II	No.
866.5765	Retinol-binding protein immunological test system	78N-2274	I	No.
866.5775	Rheumatoid factor immunological test system	78N-2275	II	No.
866.5800	Seminal fluid (sperm) immunological test system	78N-2276	I	No.
866.5820	Systemic lupus erythematosus immunological test system	78N-2277	II	No.
866.5860	Total spinal fluid immunological test system	78N-2278	II	Yes.
866.5870	Thyroid autoantibody immunological test system	78N-2279	II	No.
866.5880	Transferrin immunological test system	78N-2280	II	No.
866.5890	Inter-*alpha* trypsin inhibitor immunological test system	78N-2281	I	No.
	Subpart G—Tumor Associated Antigen Immunological Test Systems			
866.6010	Carcinoembryonic antigen (CEA) immunological test system as an aid in the detection and management of cancer		III	(1)

[1] Not proposed; statutory classification.

Summaries of Comments and FDA's Responses to Comments

1. Section 866.1620; Docket No. 78N–2114 (45 FR 27211); Antimicrobial susceptibility test disc; proposed class II.

Section 866.1640; Docket No. 78N–2115 (45 FR 27213); Antimicrobial susceptibility test powder; proposed class II.

Section 866.2050; Docket No. 78N–2118 (45 FR 27215); Staphylococcal typing bacteriophage; proposed class I.

Section 866.2300; Docket No. 78N–2124 (45 FR 27219); Multipurpose culture media; proposed class I.

Section 866.2320; Docket No. 78N–2125 (45 FR 27220); Differential culture media; proposed class I.

Section 866.2330; Docket No. 78N–2126 (45 FR 27221); Enriched culture media; proposed class I.

Section 866.2350; Docket No. 78N–2127 (45 FR 27222); Microbiological assay culture media; proposed class I.

Section 866.2360; Docket No. 78N–2128 (45 FR 27223); Selective culture media; proposed class I.

Section 866.2390; Docket No. 78N–2129 (45 FR 27223); Transport culture media; proposed class I.

Section 866.2450; Docket No. 78N–2132 (45 FR 27227); Supplement for culture media; proposed class I.

Section 866.2480; Docket No. 78N–2133 (45 FR 27227); Quality control kit for culture media; proposed class I.

Section 866.3035; Docket No. 78N–2143 (45 FR 27236); *Arizona* spp. serological reagents; proposed class I.

Section 866.3040; Docket No. 78N–2144 (45 FR 27237); *Aspergillus* spp. serological reagents; proposed class I.

Section 866.3110; Docket No. 78N–2149 (45 FR 27241); *Campylobacter fetus* serological reagents; proposed class I.

Section 866.3740; Docket No. 78N–2203 (45 FR 27286); *Streptococcus* spp. serological reagents; proposed class I.

On the proposals concerning the devices listed above, FDA received comments arguing that, because of the devices' clinical importance, those devices proposed for classification into class I should instead be classified into class II, and those devices proposed for classification into class II should instead be classified into class III. No additional data were provided in support of the comments.

FDA disagrees with the comments. The agency believes that the proposed regulations to classify those devices provided adequate support for their proposed classifications. Accordingly, the proposed regulations are being adopted as proposed, sometimes with minor clarifying changes.

2. Section 866.2300; Docket No. 78N–2124; Multipurpose culture media; proposed class I.

Section 866.2320; Docket No. 78N–2125; Differential culture media; proposed class I.

Section 866.2330; Docket No. 78N–2126; Enriched culture media; proposed class I.

Section 866.2360; Docket No. 78N–2128; Selective culture media; proposed class I.

Section 866.2390; Docket No. 78N–2129; Transport culture media; proposed class I.

In addition to the comments described above requesting that the classifications of the devices above be upgraded from those proposed due to the clinical importance of these devices, comments also suggested that the "ready to use" media listed above be classified into class II but that dried media products be in class I. No additional data were provided in support of this position.

FDA disagrees with the comments. The agency believes, however, that manufacturers, through improved labeling of these devices, should provide more information to users regarding the performance characteristics of the devices. Accordingly, except where other comments described below justified changes, the proposed regulations on the devices listed above are being adopted as proposed, sometimes with minor clarifying changes.

3. Section 866.2480; Docket No. 78N–2133; Quality control kit for culture media.

FDA published in the **Federal Register** (45 FR 27227) a proposed regulation to classify quality control kit for culture media into class I.

A comment requested that the identification of the device be expanded to include materials other than paper discs that are capable of serving as vehicles for lyophilized quality control organisms.

FDA agrees with the comment. The agency is broadening the identification of the device to include materials other than paper discs that are suitable as vehicles for lyophilized quality control organisms. Accordingly, the proposed regulation is being adopted with the necessary clarification in the identification of the device.

4. Section 866.3140; Docket No. 78N–2153; *Corynebacterium* spp. serological reagents.

FDA published in the **Federal Register** (45 FR 27244) a proposed regulation to classify *Corynebacterium* spp. serological reagents into class I. One comment was received on the proposal. The comment requested that the device be classified into class II instead of class I because of the need to differentiate the clinically important *Corynebacterium diphtheriae* from other nonpathogenic cornyeforms.

FDA disagrees with the comment. The agency recognizes the importance of being able to differentiate *Corynebacterium diphtheriae* from nonpathogenic coryneforms. However, the agency also recognizes that the

diagnosis of disease caused by *Corynebacterium diphtheriae* more often depends upon diagnostic methods other than use of serological reagents, such as culture isolation, biochemical characterization, toxigenicity tests, and morphological examination. The agency believes that general controls for the device are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

5. Section 866.3165; Docket No. 78N-2156; *Cryptococcus neoformans* serological reagents.

FDA published in the Federal Register (45FR 27246) a proposed regulation to classify *Cryptococcus neoformans* serological reagents into class II. One comment was received on the proposal. The comment recommended that the device be classified into class I. The comment noted that the recommendation of the device advisory panel that the device be classified into class II was based on a published report of unsatisfactory performance with some of these devices. The problems with these devices developed because users were required to perform a preliminary step on the applicable reagents before performing the test, i.e., the sensitization of the latex particles with *Cryptococcus neoformans* antibody. The comment noted that the current manufacturing procedures for this device have been modified to provide users with presensitized latex particles, thereby reducing the variability described in the report.

FDA partially agrees with the comment. With regard to the cited study, FDA agrees that the availability of completely manufactured reagents should reduce the observed variability of test results. However, because of the frequent reliance upon these serologic test results and the serious risk to health resulting from a misdiagnosis of cryptococcosis, FDA believes that a performance standard is necessary to assure the safety and effectiveness of these devices.

In addition, FDA notes that the identification in the proposed regulation for these devices stated that *Cryptococcus neoformans* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Cryptococcus neoformans* antibodies in serum. The words "and antisera" are erroneous and are deleted in the final rule. Accordingly, the proposed regulation is being adopted with this correction and minor clarifying changes.

6. Section 866.3175; Docket No. 78N-2157; Cytomegalovirus serological reagents.

FDA published in the Federal Register (45 FR 27248) a proposed regulation to classify cytomegalovirus serological reagents into class I. Two comments were received on the proposal. One comment requested that the device be classified into class III instead of class I based on the potential for fetal damage should infection with this virus occur during pregnancy. The second comment requested, for the same reasons, that the device be classified into class II instead of class I.

FDA partially agrees that the device should be more stringently regulated than had been proposed, but believes that performance standards, rather than premarket approval, will offer sufficient additional controls. On July 7, 1980, the agency had the comments considered by the Microbiology Device Section of the Immunology and Microbiology Devices Panel. The Section recommended that the device be classified into class II. The agency agrees with this recommendation.

Infection of humans with congenitally acquired cytomegalovirus is prevalent, but often asymptomatic. Because the antibody to this disease is often found in the general population, the diagnosis of the disease and its precise time of acute infection cannot always be established by serologic testing alone. Often other methods are used to provide a definitive diagnosis of cytomegalovirus infection. In cases where cytomegalovirus infection is diagnosed during pregnancy, it has been found that more than 95 percent of newborns that may have been infected in utero have no apparent disease at birth (Refs. 1, 2, and 3). The agency believes that general controls are insufficient to provide reasonable assurance of the safety and effectiveness of the device, but that premarket approval is not necessary to provide this assurance. Rather, performance standards are necessary to control the risks to health presented by the device and to assure the device has the desired sensitivity, specificity, and reproducibility. The agency believes that performance standards would provide resonable assurance of the safety and effectiveness of these devices. FDA also believes that sufficient reference materials, performance specifications, and evaluation methods are available to establish a performance standard for the device (Ref. 4).

Accordingly, FDA is changing the proposed regulation for cytomegalovirus serological reagents to reflect the change in classification from class I to class II and to make a minor clarifying change. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA has decided that it is unnecessary to issue a new proposal concerning this decision.

7. Section 866.3300; Docket No. 78N-2169; *Haemophilus* spp. serological reagents.

FDA published in the Federal Register (45 FR 27257) a proposed regulation to classify *Haemophilus* spp. serological reagents into class I. One comment was received on the proposal. The comment requested that classification of the devices be changed from class I to class II based on the clinical importance of detecting *Haemophilus influenzae* in cases of infant meningitis.

FDA agrees with the comment. The agency believes that the *Haemophilus* spp. serological reagents identified in the proposed regulation should be classified into class II. The agency believes that performance standards are needed to assure that the devices have the necessary sensitivity, specificity, and reproducibility to detect *Haemophilus influenzae* accurately in cases of infant meningitis. The agency believes that performance standards will provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

Accordingly, FDA is changing the proposed regulation for *Haemophilus* spp. serological reagents to reflect the change in classification from class I to class II and to make a minor clarifying change. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA has decided that it is unnecessary to issue a new proposal concerning this decision.

8. Section 866.3305; Docket No. 78N-2170; Herpes simplex virus serological reagents.

FDA published in the Federal Register (45 FR 27258) a proposed regulation to classify herpes simplex virus serological reagents into class II. Three comments were received on the proposal. All three comments expressed concern about the risks to the health of newborn infants that are associated with infection with the herpes simplex virus. Two comments requested that class III controls be applied to this device because of these risks to health and because medical practitioners rely upon the accuracy of the test results to make important clinical decisions, such as whether or not to perform a cesarean section delivery of an infant. The third comment urged that, before performance

standards are established, clinical data be obtained that compares the sensitivity and specificity of herpes simplex virus serological reagents with the accuracy of diagnosis of the infection by viral culture.

FDA agrees with the comments. On July 7, 1980, the agency had these comments considered by the Microbiology Device Section of the Immunology and Microbiology Devices Panel. The Section recommended that the direct fluorescent antibody reagents, as well as all reagents employed in more recently developed laboratory methods (e.g., enzyme immunoassays) of testing for herpes simplex virus antibodies in a patient's serum, be classified in class III. The agency agrees with this recommendation. FDA believes that, until performance standards are established and in effect for these devices, they should be classified into class III to control the risks to health that may result if these devices lack certain attributes, such as sensitivity specificity, or reproducibility.

The agency believes that the herpes simplex virus serological reagents are purported or represented to be for a use (detection of herpes simplex virus or its antibodies in specimens) which is of substantial importance in preventing impairment of human health. The agency believes that these devices present a potential unreasonable risk of illness or injury because failure to identify the virus or its antibodies may result in a serious risk to the health of the newborn infant. Incorrectly identifying the presence of herpes simplex virus may also cause a practitioner to perform an unnecessary cesarean section delivery of an infant. Premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Accordingly, FDA is changing the proposed regulation for herpes simplex virus serological reagents to reflect the change in classification from class II to class III and to make a minor clarifying change. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA has decided that it is unnecessary to issue a new proposal concerning this decision.

9. Section 866.3510; Docket No. 78N–2192; Rubella virus serological reagents.

FDA published in the **Federal Register** (45 FR 27277) a proposed regulation to classify rubella virus serological reagents into class II. Two comments were received on the proposal. Both comments requested that the classification of the device be changed from class II to class III. The requests were based on the risks to the health of the developing fetus that are associated with infections with this virus. Because irreversible medical decisions are often made on the basis of the diagnostic information derived from the use of this device, the comments suggested classification of the device into class III.

FDA agrees with the comments. Serological testing for rubella virus antibodies is often the only method available to diagnose a current rubella virus infection. A laboratory test showing a significant increase in rubella virus antibodies in serum in the first 10 weeks of pregnancy usually is associated with fetal infection. Additionally, on July 7, 1980, the agency had these comments considered by the Microbiology Device Section of the Immunology and Microbiology Devices Panel. The Section recommended that all reagents employed in the more recently developed laboratory methods for testing for rubella virus be classified into class III. The agency agrees with this recommendation and FDA is classifying into class III all of the rubella virus serological reagents, because the newer methods are based on the older methods. FDA believes that, until performance standards are established and in effect for these devices, they should be classified into class III to control the risks to health that may result if these devices lack certain attributes, such as sensitivity, specificity or reproducibility.

The agency believes that the rubella virus serological reagents are purported or represented to be for a use (identification of rubella virus antibodies in serum) which is of substantial importance in preventing impairment of human health. The agency believes that this device presents a potential unreasonable risk of illness or injury because of the serious therapeutic consequences that can follow inaccurate diagnosis. Premarket approval is necessary for the device because general controls and performance standards are insufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA also believes that there is insufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

Accordingly, FDA is changing the proposed regulation for rubella virus serological reagents to reflect the change in classification from class II to class III and to make minor clarifying changes. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA has decided that it is unnecessary to issue a new proposal concerning this decision.

10. Section 866.3720; Docket No. 78N–2202; *Streptococcus* spp. exoenzyme reagents.

FDA published in the **Federal Register** (45 FR 27286) a proposed regulation to classify *Streptococcus* spp. exoenzyme reagents into class II. One comment was received on the proposal. The comment requested that this device be classified into class I instead of class II. The request for change in classification was based on alleged misinterpretation by the reviewing Panel of test results published in the scientific articles cited in support of the proposed classification regulation for the device.

FDA disagrees with the comment. The agency has reviewed the scientific articles in question. FDA believes that the conclusions reached by the Panel and cited in the proposed regulation are valid, particularly those conclusions that suggest that the device lacks adequate sensitivity and has excessive lot-to-lot variations in performance. Therefore, the agency believes that performance standards are necessary to assure the safety and effectiveness of the device. Accordingly, the proposed regulation is being adopted without change.

11. Section 866.3780; Docket No. 78N–2204; *Toxoplasma gondii* serological reagents.

FDA published in the **Federal Register** (45 FR 27287) a proposed regulation to classify *Toxoplasma gondii* serological reagents into class II. One comment was received on the proposal. The comment requested that the device be classified into class III instead of class II because of the potential for fetal damage should infection with *Toxoplasma gondii* occur during pregnancy.

FDA disagrees with the comment. On July 7, 1980, the agency had the comment considered by the Microbiology Device Section of the Immunology and Microbiology Devices Panel. The Section recommended that the device be classified into class II as proposed. Congenitally acquired *Toxoplasma gondii* is prevalent, but that condition is often asymptomatic. Because the antibody to this disease is often found in the general population, the diagnosis of the disease and its precise time of acute infection cannot always be established by serologic testing alone. Often other methods are used to provide a definitive diagnosis of acute toxoplasmosis. The agency believes that the data and views presented in the proposed regulation for

these devices adequately support their classification into class II. The agency also believes that performance standards would provide reasonable assurance of the safety and effectiveness of the device. FDA believes that sufficient reference materials, performance specifications, and evaluation methods are available to establish performance standards for these devices. Accordingly, the proposed regulation is being adopted with minor clarifying changes.

12. Section 866.3900; Docket No. 78N–2210; Varicella-zoster virus serological reagents.

FDA published in the **Federal Register** (45 FR 27293) a proposed regulation to classify varicella-zoster serological reagents into class I. One comment was received on the proposal. The comment requested that the device be classified into class III instead of class I because of the potential for fetal damage should infection with varicella-zoster virus occur during pregnancy.

FDA disagrees with the comment. On July 7, 1980, the agency had the comment considered by the Microbiology Device Section of the Immunology and Microbiology Devices Panel. The Section recommended that the device be classified into class II. FDA agrees with the recommendation. Although there is a potential risk to the fetus should infection with the varicella-zoster virus occur during pregnancy, in many cases there is no injury to the fetus due to a diagnosis of varicella-zoster virus infection during pregnancy. The agency believes that performance standards would provide reasonable assurance of the safety and effectiveness of the device and assure that the device has the desired sensitivity, specificity, and reproducibility. The agency also believes that sufficient reference materials, performance specifications, and evaluation methods are available to establish performance standards for these devices (Ref. 4).

Accordingly, FDA is changing the proposed regulation for varicella-zoster virus serological reagents to reflect the change in classification from class I to class II and to make a clarification in the name and identification of the device. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA has decided that it is unnecessary to issue a new proposal concerning this decision.

13. Section 866.5065; Docket No. 78N–2222; Human allotypic marker immunological test system.

FDA published in the **Federal Register** (45 FR 27302) a proposed regulation to classify the human allotypic marker immunological test system into class I. One comment was received on the proposal. The comment stated that the majority of immunoglobulin allotypic reagents are used in forensic medicine and paternity testing and errors caused by incorrect specificity may be of legal significance. The comment suggested classification of the device into class II to provide a performance standard to reduce the chance of errors.

FDA disagrees with this comment. The agency believes that the data included in the proposed regulation and the intended use of the device supports classification into class I. Accordingly, the proposed regulation is being adopted with a minor clarifying change.

14. Section 866.5270; Docket No. 78N–2238; C-reactive protein immunological test system.

FDA published in the **Federal Register** (45 FR 27318) a proposed regulation to classify the C-reactive protein immunological test system into class II. One comment was received on the proposal. The comment alleged that tests for C-reactive protein are of little clinical usefulness and are rarely used in diagnosis of diseases. Therefore, the comment urged that C-reactive protein immunological test systems be in class I instead of class II.

FDA disagrees with this comment. The agency believes that tests for C-reactive protein measurement aid in the evaluation of the amount of injury to body tissues. FDA believes that a performance standard, that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity, is necessary to minimize any inaccurate diagnostic information. The agency believes that the intended use of the device supports its classification into class II. Accordingly, the proposed regulation is being adopted with minor clarifying changes.

15. Section 866.5520; Docket No. 78N–2257; Immunoglobulin G (Fab fragment specific) immunological test system.

FDA published in the **Federal Register** (45 FR 27336) a proposed regulation to classify the immunoglobulin G (Fab fragment specific) immunological test system into class II. One comment was received on the proposal. The comment suggested that an equally important and related device, the $F(ab')_2$, used in lymphocyte subpopulation identification, also be classified by FDA.

FDA disagrees with this comment. The agency believes that $F(ab')_2$ has been used only for research purposes and that the safety and effectiveness of the device in the diagnosis or treatment of human disease has not been established. Therefore, the classification of $F(ab')_2$ is inappropriate at this time. Because the comment did not address the proposed regulation to classify the immunoglobulin G (Fab fragment specific) immunological test system, the proposed regulation is being adopted with a minor clarifying change.

16. Section 866.5860; Docket No. 78N–2278; Total spinal fluid immunological test system.

FDA published in the **Federal Register** (45 FR 27356) a proposed regulation to classify the total spinal fluid immunological test system into class I. One comment was received on the proposal. The comment suggested that the device be classified into class II instead of class I because the sampling of spinal fluid alone involves significant patient risk and because this device is used in the diagnosis of various diseases of the nervous system, including multiple sclerosis, in addition to the uses of the device described in the proposed regulation.

FDA agrees with the comment. Although the agency believes that the risks to patients from collection of samples of spinal fluid alone would not be a basis for a change in the classification of the device, FDA agrees that measurement of spinal fluid proteins by immunochemical techniques has proven useful as an aid in the diagnosis of multiple sclerosis. Ratios of serum immunoglobulin I_gG and spinal fluid immunoglobulin I_gG in association with albumin levels may be important in diagnosis of other diseases of the nervous system. The agency believes that performance standards are necessary to assure the safety and effectiveness of the device and to assure the device has the desired sensitivity, specificity, and reproducibility. The agency also believes that there is sufficient information to establish a performance standard for these devices.

Accordingly, FDA is changing the proposed regulation for the total spinal fluid immunological test system to reflect the change in classification from class I to class II and to make a minor clarifying change. For the reasons discussed above in "Changes in Classification in Final Regulations," FDA has decided that it is unnecessary to issue a new proposal concerning this decision.

References

The following information has been placed in the Dockets Management Branch (formerly the Hearing Clerk's office) (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Melish, M. E. and J. B. Hanshaw, "Congenital Cytomegalovirus Infection: Developmental Progess of Infants Detected by Routine Screening," *American Journal of Diseases in Children*, 126:190–194, 1973.

2. Reynolds, D. W., et al., "Inapparent Congenital Cytomegalovirus Infection With Elevated Cord I_gM Levels, "*New England Journal of Medicine*, 290:219–296, 1974.

3. Starr, J. B., R. D. Bart, and E. Gold, "Inapparent Congenital Cytomegalovirus Infection," *New England Journal of Medicine*, 282:1075–1077, 1970.

4. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents, "Vol. 2, 4th Ed., Center for Desease Control, Public Health Service, Department of Health and Human Services, BIII–1–11, 1974.

List of Subjects in 21 CFR Part 866

Immunology and microbiology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 520(1), 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 360j(1), 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Chapter I of Title 21 of the Code of Federal Regulations is amended by adding new Part 866, to read as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

Subpart A—General Provisions

Sec.
866.1 Scope.

Subpart B—Diagnostic Devices

866.1620 Antimicrobial susceptibility test disc.
866.1640 Antimicrobial susceptibility test powder.
866.1700 Culture medium for antimicrobial susceptibility tests.

Subpart C—Microbiology Devices

866.2050 Staphylococcal typing bacteriophage.
866.2120 Anaerobic chamber.
866.2160 Coagulase plasma.
866.2170 Automated colony counter.
866.2180 Manual colony counter.
866.2300 Multipurpose culture medium.
866.2320 Differential culture medium.
866.2330 Enriched culture medium.
866.2350 Microbiological assay culture medium.
866.2360 Selective culture medium.
866.2390 Transport culture medium.
866.2410 Culture medium for pathogenic *Neisseria* spp.
866.2420 Oxidase screening test for gonorrhea.
866.2440 Automated medium dispensing and stacking device.
866.2450 Supplement for culture media.
866.2480 Quality control kit for culture media.
866.2500 Microtiter diluting and dispensing device.
866.2540 Microbiological incubator.
866.2560 Microbial growth monitor.
866.2580 Gas-generating device.
866.2600 Wood's fluorescent lamp.
866.2660 Microorganism differentiation and identification device.
866.2850 Automated zone reader.
866.2900 Microbiological specimen collection and transport device.

Subpart D—Serological Reagents

866.3010 *Acinetobacter calcoaceticus* serological reagents.
866.3020 Adenovirus serological reagents.
866.3035 *Arizona* spp. serological reagents.
866.3040 *Aspergillus* spp. serological reagents.
866.3060 *Blastomyces dermatitidis* serological reagents.
866.3065 *Bordetella* spp. serological reagents.
866.3085 *Brucella* spp. serological reagents.
866.3110 *Campylobacter fetus* serological reagents.
866.3120 Chlamydia serological reagents.
866.3125 *Citrobacter* spp. serological reagents.
866.3135 *Coccidioides immitis* serological reagents.
866.3140 *Corynebacterium* spp. serological reagents.
866.3145 Coxsackievirus serological reagents.
866.3165 *Cryptococcus neoformans* serological reagents.
866.3175 Cytomegalovirus serological reagents.
866.3200 *Echinococcus* spp. serological reagents.
866.3205 Echovirus serological reagents.
866.3220 *Entamoeba histolytica* serological reagents.
866.3235 Epstein-Barr virus serological reagents.
866.3240 Equine encephalomyelitis virus serological reagents.
866.3250 *Erysipelothrix rhusiopathiae* serological reagents.
866.3255 *Escherichia coli* serological reagents.
866.3270 *Flavobacterium* spp. serological reagents.
866.3280 *Francisella tularensis* serological reagents.
866.3290 Gonococcal antibody test (GAT).
866.3300 *Haemophilus* spp. serological reagents.
866.3305 Herpes simplex virus serological reagents.
866.3320 *Histoplasma capsulatum* serological reagents.
866.3330 Influenza virus serological reagents.
866.3340 *Klebsiella* spp. serological reagents.
866.3350 *Leptospira* spp. serological reagents.
866.3355 *Listeria* spp. serological reagents.
866.3360 Lymphocytic choriomeningitis virus serological reagents.
866.3370 *Mycobacterium tuberculois* immunofluorescent reagents.
866.3375 *Mycoplasma* spp. serological reagents.
866.3380 Mumps virus serological reagents.
866.3390 *Neisseria* spp. direct serological test reagents.
866.3400 Parainfluenza virus serological reagents.
866.3405 Poliovirus serological reagents.
866.3410 *Proteus* spp. (Weil-Felix) serological reagents.
866.3415 *Pseudomonas* spp. serological reagents.
866.3460 Rabiesvirus immunofluorescent reagents.
866.3470 Reovirus serological reagents.
866.3480 Respiratory syncytial virus serological reagents.
866.3490 Rhinovirus serological reagents.
866.3500 Rickettsia serological reagents.
866.3510 Rubella virus serological reagents.
866.3520 Rubeola (measles) virus serological reagents.
866.3550 *Salmonella* spp. serological reagents.
866.3600 *Schistosoma* spp. serological reagents.
866.3630 *Serratia* spp. serological reagents.
866.3660 *Shigella* spp. serological reagents.
866.3680 *Sporothrix schenckii* serological reagents.
866.3700 *Staphylococcus aureus* serological reagents.
866.3720 *Streptococcus* spp. exoenzyme reagents.
866.3740 *Streptococcus* spp. serological reagents.
866.3780 *Toxoplasma gondii* serological reagents.
866.3820 *Treponema pallidum* nontreponemal test reagents.
866.3830 *Treponema pallidum* treponemal test reagents.
866.3850 *Trichinella spiralis* serological reagents.
866.3870 *Trypansoma* spp. serological reagents.
866.3900 Varicella-zoster virus serological reagents.
866.3930 *Vibrio cholerae* serological reagents.

Subpart E—Immunology Laboratory Equipment and Reagents

866.4100 Complement reagent.
866.4500 Immunoelectrophoresis equipment.
866.4520 Immunofluorometer equipment.
866.4540 Immunonephelometer equipment.
866.4600 Ouchterlony agar plate.
866.4800 Radial immunodiffusion plate.
866.4830 Rocket immunoelectrophoresis equipment.
866.4900 Support gel.

Subpart F—Immunological Test Systems

866.5040 Albumin immunological test system.
866.5060 Prealbumin immunological test system.
866.5065 Human allotypic marker immunological test system.
866.5080 *Alpha*-1-antichymotrypsin immunological test system.
866.5090 Antimitochondrial antibody immunological test system.
866.5100 Antinuclear antibody immunological test system.
866.5110 Antiparietal antibody immunological test system.
866.5120 Antismooth muscle antibody immunological test system.

Sec.
866.5130 *Alpha*-1-antitrypsin immunological test system.
866.5150 Bence-Jones proteins immunological test system.
866.5160 *Beta-globulin* immunological test system.
866.5170 Breast milk immunological test system.
866.5200 Carbonic anhydrase B and C immunological test system.
866.5210 Ceruloplasmin immunological test system.
866.5220 Cohn fraction II immunological test system.
866.5230 Colostrum immunological test system.
866.5240 Complement components immunological test system.
866.5250 Complement C_1 inhibitor (inactivator) immunological test system.
866.5260 Complement C_{3b} inactivator immunological test system.
866.5270 C-reactive protein immunological test system.
866.5320 Properidin factor B immunological test system.
866.5330 Factor XIII, A, S, immunological test system.
866.5340 Ferritin immunological test system.
866.5350 Fibrinopeptide A immunological test system.
866.5360 Cohn fraction IV immunological test system.
866.5370 Cohn fraction V immunological test system.
866.5380 Free secretory component immunological test system.
866.5400 *Alpha*-globulin immunological test system.
866.5420 *Alpha*-1-glycoproteins immunological test system.
866.5425 *Alpha*-2-glycoproteins immunological test system.
866.5430 *Beta*-2-glycoprotein I immunological test system.
866.5440 *Beta*-2-glycoprotein III immunological test system.
866.5460 Haptoglobin immunological test system.
866.5470 Hemoglobin immunological test system.
866.5490 Hemopexin immunological test system.
866.5500 Hypersensitivity pneumonitis immunological test system.
866.5510 Immunoglobulins A, G, M, D, and E immunological test system.
866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.
866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.
866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.
866.5550 Immunoglobulin (light chain specific) immunological test system.
866.5560 Lactic dehydrogenase immunological test system.
866.5570 Lactoferrin immunological test system.
866.5580 *Alpha*-1-lipoprotein immunological test system.
866.5590 Lipoprotein X immunological test system.
866.5600 Low-density lipoprotein immunological test system.
866.5620 *Alpha*-2-macroglobulin immunological test system.
866.5630 *Beta*-2-microglobulin immunological test system.
866.5640 Infectious mononucleosis immunological test system.
866.5660 Multiple autoantibodies immunological test system.
866.5680 Myoglobin immunological test system.
866.5700 Whole human plasma or serum immunological test system.
866.5715 Plasminogen immunological test system.
866.5735 Prothrombin immunological test system.
866.5750 Radioallergosorbent (RAST) immunological test system.
866.5765 Retinol-binding protein immunological test system.
866.5775 Rheumatoid factor immunological test system.
866.5800 Seminal fluid (sperm) immunological test system.
866.5820 Systemic lupus erythematosus immunological test system.
866.5860 Total spinal fluid immunological test system.
866.5870 Thyroid autoantibody immunological test system.
866.5880 Transferrin immunological test system.
866.5890 Inter-*alpha* trypsin inhibitor immunological test system.

Subpart G—Tumor Associated Antigen Immunological Test Systems

866.6010 Carcinoembryonic antigen (CEA) immunological test system as an aid in the detection and management of cancer.

Authority: Secs. 513, 520(1), 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 360j(1), 371(a)).

Subpart A—General Provisions

§ 866.1 Scope.

(a) This part sets forth the classification of immunology and microbiology devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provisions of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

Subpart B—Diagnostic Devices

§ 866.1620 Antimicrobial susceptibility test disc.

(a) *Identification.* An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc-agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.

(b) *Classification.* Class II (performance standards).

§ 866.1640 Antimicrobial susceptibility test powder.

(a) *Identification.* An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used to determine the antimicrobial agent of choice in the treatment of bacterial diseases.

(b) *Classification.* Class II (performance standards).

§ 866.1700 Culture medium for antimicrobial susceptibility tests.

(a) *Identification.* A culture medium for antimicrobial susceptibility tests is a device intended for medical purposes that consists of any medium capable of supporting the growth of many of the bacterial pathogens that are subject to antimicrobial susceptibility tests. The medium should be free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.

(b) *Classification.* Class II (performance standards).

Subpart C—Microbiology Devices

§ 866.2050 Staphylococcal typing bacteriophage.

(a) *Identification.* A staphylococcal typing bacteriophage is a device consisting of a bacterial virus intended for medical purposes to identify pathogenic staphylococcal bacteria through use of the bacteria's susceptibility to destruction by the virus.

Test results are used principally for the collection of epidemiological information.

(b) *Classification.* Class I (general controls).

§ 866.2120 Anaerobic chamber.

(a) *Identification.* An anaerobic chamber is a device intended for medical purposes to maintain an anaerobic (oxygen free) environment. It is used to isolate and cultivate anaerobic microorganisms.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 866.2160 Coagulase plasma.

(a) *Identification.* Coagulase plasma is a device that consists of freeze-dried animal or human plasma that is intended for medical purposes to perform coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus *Staphylococcus* and provide epidemiological information on disease caused by these microorganisms.

(b) *Classification.* Class II (performance standards).

§ 866.2170 Automated colony counter.

(a) *Identification.* An automated colony counter is a mechanical device intended for medical purposes to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls).

§ 866.2180 Manual colony counter.

(a) *Identification.* A manual colony counter is a device intended for medical purposes that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 866.2300 Multipurpose culture medium.

(a) *Identification.* A multipurpose culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes for the cultivation and identification of several types of pathogenic microorganisms without the need of additional nutritional supplements. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class I (general controls).

§ 866.2320 Differential culture medium.

(a) *Identification.* A differential culture medium is a device that consists primarily of liquid biological materials intended for medical purposes to cultivate and identify different types of pathogenic microorganisms. The identification of these microorganisms is accomplished by the addition of a specific biochemical component(s) to the medium. Microorganisms are identified by a visible change (e.g., a color change) in a specific biochemical component(s) which indicates that specific metabolic reactions have occurred. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class I (general controls).

§ 866.2330 Enriched culture medium.

(a) *Identification.* An enriched culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate and identify fastidious microorganisms (those having complex nutritional requirements). The device consists of a relatively simple basal medium enriched by the addition of such nutritional components as blood, blood serum, vitamins, and extracts of plant or animal tissues. The device is used in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

§ 866.2350 Microbiological assay culture medium.

(a) *Identification.* A microbiological assay culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate selected test microorganisms in order to measure by microbiological procedures the concentration in a patient's serum of certain substances, such as amino acids, antimicrobial agents, and vitamins. The concentration of these substances is measured by their ability to promote or inhibit the growth of the test organism in the innoculated medium. Test results aid in the diagnosis of disease resulting from either deficient or excessive amounts of these substances in a patient's serum. Tests results may also be used to monitor the effects of the administration of certain antimicrobial drugs.

(b) *Classification.* Class I (general controls).

§ 866.2360 Selective culture medium.

(a) *Identification.* A selective culture medium is a device that consists primarily of liquid or solid biological materials intended for medical purposes to cultivate and identify certain pathogenic microorganisms. The device contains one or more components that suppress the growth of certain microorganisms while either promoting or not affecting the growth of other microorganisms. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

§ 866.2390 Transport culture medium.

(a) *Identification.* A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

§ 866.2410 Culture medium for pathogenic Neisseria spp.

(a) *Identification.* A culture medium for pathogenic *Neisseria* spp. is a device that consists primarily of liquid or solid

biological materials used to cultivate and identify pathogenic *Neisseria* spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria*, such as epidemic cerebrospinal meningitis, other meningococcal disease, and gonorrhea, and also provides epidemiological information on these microorganisms.

(b) *Classification.* Class II (performance standards).

§ 866.2420 Oxidase screening test for gonorrhea.

(a) *Identification.* An oxidase screening test for gonorrhea is an in vitro device that consists of the articles intended to identify by chemical reaction, cytochrome oxidase, an oxidizing enzyme that is associated with certain bacteria including *Neisseria gonorrhoeae*. A sample of a male's urethral discharge is obtained on a swab which is placed into a wetting agent containing an ingredient that will react with cytochrome oxidase. When cytochrome oxidase is present, the swab turns a dark purple color within 3 minutes. Because it is unlikely that cytochrome oxidase-positive organisms other than *Neisseria gonorrhoeae* are present in the urethral discharge of males, the identification of cytochrome oxidase with this device indicates presumptive infection of the patient with the causative agent of gonorrhea.

(b) *Classification.* Class III (premarket approval) (transitional device).

§ 866.2440 Automated medium dispensing and stacking device.

(a) *Identification.* An automated medium dispensing and stacking device is a device intended for medical purposes to dispense a microbiological culture medium into petri dishes and then mechanically stack the petri dishes.

(b) *Classification.* Class I (general controls). This device is exempt from the premarket notification procedures in Subpart E of Part 807. This device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 866.2450 Supplement for culture media.

(a) *Identification.* A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is intended for medical purposes to enhance the growth of fastidious microorganisms (those having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.

(b) *Classification.* Class I (general controls).

§ 866.2480 Quality control kit for culture media.

(a) *Identification.* A quality control kit for culture media is a device that consists of paper discs (or other suitable materials), each impregnated with a specified, freeze-dried, viable microorganism, intended for medical purposes to determine if a given culture medium is able to support the growth of that microorganism. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

§ 866.2500 Microtiter diluting and dispensing device.

(a) *Identification.* A microtiter diluting an dispensing device is a mechanical device intended for medical purposes to dispense or serially dilute very small quantities of biological or chemical reagents for use in various diagnostic procedures.

(b) *Classification.* Class I (general controls).

§ 866.2540 Microbiological incubator.

(a) *Identification.* A microbiological incubator is a device with various chambers or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained. It is intended for medical purposes to cultivate microorganisms and aid in the diagnosis of disease.

(b) *Classification.* Class I (general controls). This device is exempt from premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 866.2560 Microbial growth monitor.

(a) *Identification.* A microbial growth monitor is a device intended for medical purposes that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease caused by pathogenic microorganisms.

(b) *Classification.* Class I (general controls).

§ 866.2580 Gas-generating device.

(a) *Identification.* A gas-generating device is a device intended for medical purposes that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

§ 866.2600 Wood's fluorescent lamp.

(a) *Identification.* A Wood's fluorescent lamp is a device intended for medical purposes to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

§ 866.2660 Microorganism differentiation and identification device.

(a) *Identification.* A microorganism differentiation and identification device is a device intended for medical purposes that consists of one or more components, such as differential culture media, biochemical reagents, and paper discs or paper strips impregnated with test reagents, that are usually contained in individual compartments and used to differentiate and identify selected microorganisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

§ 866.2850 Automated zone reader.

(a) *Identification.* An automated zone reader is a mechanical device intended for medical purposes to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in decisionmaking respecting the treatment of disease.

(b) *Classification.* Class I (general controls).

§ 866.2900 Microbiological specimen collection and transport device.

(a) *Identification.* A microbiological specimen collection and transport device is a specimen collecting chamber

intended for medical purposes to preserve the viability or integrity of microorganisms in specimens during storage of specimens after their collection and during their transport from the collecting area to the laboratory. The device may be labeled or otherwise represented as sterile. The device aids in the diagnosis of disease caused by pathogenic microorganisms.

(b) *Classification.* Class I (general controls).

Subpart D—Serological Reagents

§ 866.3010 Acinetobacter calcoaceticus serological reagents.

(a) *Identification. Acinetobacter calcoaceticus* serological reagents are devices that consist of *Acinetobacter calcoaceticus* antigens and antisera used to identify this bacterium from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by the bacterium *Acinetobacter calcoaceticus* and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

(b) *Classification.* Class I (general controls).

§ 866.3020 Adenovirus serological reagents.

(a) *Identification.* Adenovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to adenovirus in serum. Additionally, some of these reagents consist of adenovirus antisera conjugated with a fluorescent dye and are used to identify adenoviruses directly from clinical specimens. The identification aids in the diagnosis of disease caused by adenoviruses and provides epidemiological information on these diseases. Adenovirus infections may cause pharyngitis (inflammation of the throat), acute respiratory diseases, and certain external diseases of the eye (e.g., conjunctivitis).

(b) *Classification.* Class I (general controls).

§ 866.3035 Arizona spp. serological reagents.

(a) *Identification. Arizona* spp. serological reagents are devices that consist of antisera and antigens used to identify *Arizona* spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Arizona* and provides epidemiological information on diseases caused by these microorganisms. *Arizona* spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).

(b) *Classification.* Class I (general controls).

§ 866.3040 Aspergillus spp. serological reagents.

(a) *Identification. Aspergillus* spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify antibodies to *Aspergillus* spp. in serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genus *Aspergillus.* Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lessions in the skin, ear, eyeball cavity, nasal sinuses, lungs, and occasionally the bones.

(b) *Classification.* Class I (general controls).

§ 866.3060 Blastomyces dermatitidis serological reagents.

(a) *Identification. Blastomyces dermatitidis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Blastomyces determatitidis* in ssrum. The identification aids in the diagnosis of blastomycosis caused by the fungus *Blastomyces dermatitidis.* Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(b) *Classification.* Class II (performance standards).

§ 866.3065 Bordetella spp. serological reagents.

(a) *Identification. Bordetella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify *Bordetella* spp. from cultured isolates or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Bordetella* and provides epidemiological information on these diseases. *Bordetella* spp. cause whooping cough (*Bordetella pertussis*) and other similiarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

(b) *Classification.* Class I (general controls).

§ 866.3085 Brucella spp. serological reagents.

(a) *Identification. Brucella* spp. serological reagents are devices that consist of antigens and antisera used for serological identification of *Brucella* spp. from cultured isolates derived from clinical specimens or to identify antibodies to *Brucella* spp. in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Brucella* spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genus *Brucella* and provides epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class II (performance standards).

§ 866.3110 Campylobacter fetus serological reagents.

(a) *Identification. Campylobacter fetus* serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Campylobacter fetus* from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium and provides epidemiological information on these diseases. *Campylobacter fetus* is a frequent cause of abortion in sheep and cattle and is sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

(b) *Classification.* Class I (general controls).

§ 866.3120 Chlamydia serological reagents.

(a) *Identification.* Chlamydia serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to chlamydia in serum. Additionally, some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye used to identify chlamydia directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* and provides epidemiological information on these diseases. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and

trachoma (a chronic disease of the eye and eyelid).

(b) *Classification.* Class I (general controls).

§ 866.3125 Citrobacter spp. serological reagents.

(a) *Identification. Citrobacter* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Citrobacter* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Citrobacter* and provides epidemiological information on diseases caused by these microorganisms. *Citrobacter* spp. have occasionally been associated with urinary tract infections.

(b) *Classification.* Class I (general controls).

§ 866.3135 Coccidioides immitis serological reagents.

(a) *Identification. Coccidioides immitis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Coccidioides immitis* in serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genus *Coccidioides* and provides epidemiological information on diseases caused by this microorganism. An infection with *Coccidioides immitis* produces symptoms varying in severity from those accompanying the common cold to those of influenza.

(b) *Classification.* Class II (performance standards).

§ 866.3140 Corynebacterium spp. serological reagents.

(a) *Identification. Corynebacterium* spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Corynebacterium* spp. from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Corynebacterium* and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus, *Corynebacterium diphtheriae*, causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin, and are either nonpathogenic or have an uncertain role.

(b) *Classification.* Class I (general controls).

§ 866.3145 Coxsackievirus serological reagents.

(a) *Identification.* Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to coxsackievirus in serum. Additionally, some of these reagents consist of coxsackievirus antisera conjugated with a fluorescent dye that are used to identify coxsackievirus from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).

(b) *Classification.* Class I (general controls).

§ 866.3165 Cryptococcus neoformans serological reagents.

(a) *Identification. Cryptococcus neoformans* serological reagents are devices that consist of antigens used in serological tests to identify antibodies to *Cryptococcus neoformans* in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify *Cryptococcus neoformans* directly from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cryptococcosis and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

(b) *Classification.* Class II (performance standards).

§ 866.3175 Cytomegalovirus serological reagents.

(a) *Identification.* Cytomegalovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to cytomegalovirus in serum. The identification aids in the diagnosis of diseases caused by cytomegaloviruses (principally cytomegalic inclusion disease) and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitis, and an infectious mononucleosis-like syndrome.

(b) *Classification.* Class II (performance standards).

§ 866.3200 Echinococcus spp. serological reagents.

(a) *Identification. Echinococcus* spp. serological reagents are devices that consist of *Echinococcus* spp. antigens and antisera used in serological tests to identify antibodies to *Echinococcus* spp. in serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genus *Echinococcus* and provides epidemiological information on this disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organisms.

(b) *Classification.* Class I (general controls).

§ 866.3205 Echovirus serological reagents.

(a) *Identification.* Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to echovirus in serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

(b) *Classification.* Class I (general controls).

§ 866.3220 Entamoeba histolytica serological reagents.

(a) *Identification. Entamoeba histolytica* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Entamoeba histolytica* in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Entamoeba histolytica* directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic

protozoan parasite *Entamoeba histolytica* and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.

(b) *Classification.* Class I (performance standards).

§ 866.3235 Epstein-Barr virus serological reagents.

(a) *Identification.* Epstein-Barr virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to Epstein-Barr virus in serum. The identification aids in the diagnosis of Epstein-Barr virus infections and provides epidemiological information on diseases caused by these viruses. Epstein-Barr viruses are thought to cause infectious mononucleosis and have been associated with Burkitt's lymphoma (a tumor of the jaw in African children and young adults) and postnasal carcinoma (cancer).

(b) *Classification.* Class I (general controls).

§ 866.3240 Equine encephalomyelitis virus serological reagents.

(a) *Identification.* Equine encephalomyelitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antobodies to equine encephalomyelitis virus in serum. The identification aids in the diagnosis of diseases caused by equine encephalomyelitis viruses and provides epidemiological information on these viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects, such as mosquitos and ticks, and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.

(b) *Classification.* Class I (general controls).

§ 866.3250 Erysipelothrix rhusiopathiae serological reagents.

(a) *Identification. Erysipelothrix rhusiopathiae* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Erysipelothrix rhusiopathiae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Erysipelothrix*. This organism is responsible for a variety of inflammations of the skin following skin abrasions from contact with fish, shellfish, or poultry.

(b) *Classification.* Class I (general controls).

§ 866.3255 Escherichia coli serological reagents.

(a) *Identification. Escherichia coli* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Escherichia coli* from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Escherichia coli* antisera conjugated with a fluorescent dye used to identify *Escherichia coli* directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by this bacterium belonging to the genus *Escherichia*, and provides epidemiological information on deseased causes by this microorganism. Although *Escherichia coli* constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually nonpathogenic, those strains which are pathogenic may cause urinary tract infections or epidemic diarrheal disease, especially in children.

(b) *Classification.* Class I (general controls).

§ 866.3270 Flavobacterium spp. serological reagents.

(a) *Identification. Flavobacterium* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Flavobacteriuim* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Flavobacterium* and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. *Flavobacterium meningosepticum* is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and meningitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

(b) *Classification.* Class I (general controls).

§ 866.3280 Francisella tularensis serological reagents.

(a) *Identification. Francisella tularensis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Francisella tularensis* in serum or to identify *Francisella tularensis* in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Francisella tularensis* directly from clinical specimens. The identification aids in the diagnosis of tularemia caused by *Francisella tularensis* and provides epidemiological information on this disease. Tularemia is a desease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.

(b) *Classification.* Class II (performance standards).

§ 866.3290 Gonococcal antibody test (GAT).

(a) *Identification.* A gonococcal antibody test (GAT) is an in vitro device that consists of the reagents intended to identify by immunochemical techniques, such as latex agglutination, indirect fluorescent antibody, or radioimmunoassay, antibodies to *Neisseria gonorrhoeae* in sera of asymptomatic females at low risk of infection. Identification of antibodies with this device may indicate past or present infection of the patient with *Neisseria gonorrhoeae.*

(b) *Classification.* Class III (premarket approval) (transitional device).

§ 866.3300 Haemophilus spp. serological reagents.

(a) *Identification. Haemophilus* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, that are used in serological tests to identify *Haemophilus* spp. directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Haemophilus* and provides epidemiological information on diseases cause by these microorganisms. Diseases most often caused by *Haemophilus* spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal desease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

(b) *Classification.* Class II (performance standards).

§ 866.3305 Herpes simplex virus serological reagents.

(a) *Identification.* Herpes simplex virus serological reagents are devices that consist of antigens and antisera

used in various serological tests to identify antibodies to herpes simplex virus in serum. Additionally, some of the reagents consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify herpes simplex virus directly from clinical specimens or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain). Neonatal herpes virus infections range from an mild infection to a severe generalized disease with a fatal outcome.

(b) *Classification.* Class III (premarket approval).

§ 866.3320 Histoplasma capsulatum serological reagents.

(a) *Identification. Histoplasma capsulatum* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Histoplasma capsulatum* in serum. Additionally, some of these reagents consist of *Histoplasma capsulatum* antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Histoplasma capsulatum* from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genus *Histoplasma* and provides epidemiological information on the diseases caused by this fungus. Histoplasmosis usually is a mild and often asymptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and organs.

(b) *Classification.* Class II (performance standards).

§ 866.3330 Influenza virus serological reagents.

(a) *Identification.* Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to influenza in serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

(b) *Classification.* Class I (general controls).

§ 866.3340 Klebsiella spp. serological reagents.

(a) *Identification. Klebsiella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify *Klebsiella* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Klebsiella* and provides epidemiological information on these diseases. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

(b) *Classification.* Class I (general controls).

§ 866.3350 Leptospira spp. serological reagents.

(a) *Identification. Leptospira* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Leptospira* spp. in serum or identify *Leptospira* spp. from cultured isolates derived from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify *Leptospira* spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genus *Leptospira* and provides epidemiological information on this disease. *Leptospira* infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

(b) *Classification.* Class II (performance standards).

§ 866.3355 Listeria spp. serological reagents.

(a) *Identification. Listeria* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Listeria* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Listeria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Listeria* spp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus *Listeria*, and provides epidemiological information on diseases caused by these microorganisms. *Listeria monocytogenes*, the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for infants before or after birth.

(b) *Classification.* Class I (general controls).

§ 866.3360 Lymphocytic choriomeningitis virus serological reagents.

(a) *Identification.* Lymphocytic choriomeningitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to lymphocytic choriomeningitis virus in serum. The identification aids in the diagnosis of lymphocytic choriomeningitis virus infections and provides epidemiological information on diseases caused by these viruses. Lymphocytic choriomeningitis viruses usually cause a mild cerebral meningitis (inflammation of membranes that envelop the brain) and occasionally a mild pneumonia, but in rare instances may produce severe and even fatal illnesses due to complications from cerebral meningitis and pneumonia.

(b) *Classification.* Class I (general controls).

§ 866.3370 Mycobacterium tuberculosis immunofluorescent reagents.

(a) *Identification. Mycobacterium tuberculosis* immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Mycobacterium tuberculosis* directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. *Mycobacterium tuberculosis* is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

(b) *Classification.* Class I (general controls).

§ 866.3375 Mycoplasma spp. serological reagents.

(a) *Identification. Mycoplasma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Mycoplasma* spp. in serum. Additionally, some of these reagents consist of *Mycoplasma* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Mycoplasma* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused

by bacteria belonging to the genus *Mycoplasma* and provides epidemiological information on diseases caused by these microorganisms. *Mycoplasma* spp. are associated with inflammatory conditions of the urinary and respiratory tracts, the genitals, and the mouth. The effects in humans of infection with *Mycoplasma pneumoniae* range from inapparent infection to mild or severe upper respiratory disease, ear infection, and bronchial pneumonia.

(b) *Classification.* Class I (general controls).

§ 866.3380 Mumps virus serological reagents.

(a) *Identification.* Mumps virus serological reagents consist of antigens and antisera used in serological tests to identify antibodies to mumps virus in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used in serological tests to identify mumps viruses from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of mumps and provides epidemiological information of mumps. Mumps is an acute contagious disease, particularly in children, characterized by an enlargement of one or both of the parotid glands (glands situated near the ear), although other organs may also be involved.

(b) *Classification.* Class I (general controls).

§ 866.3390 Neisseria spp. direct serological test reagents.

(a) *Identification. Neisseria* spp. direct serological test reagents are devices that consist of antigens and antisera used in serological tests to identify *Neisseria* spp. from cultured isolates. Additionally, some of these reagents consist of *Neisseria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) which may be used to detect the presence of *Neisseria* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria*, such as epidemic cerebrospinal meningitis, meningococcal disease, and gonorrhea, and also provides epidemiological information on diseases caused by these microorganisms. The device does not include products for the detection of gonorrhea in humans by indirect methods, such as detection of antibodies or of oxidase produced by gonococcal organisms.

(b) *Classification.* Class II (performance standards).

§ 866.3400 Parainfluenza virus serological reagents.

(a) Identification. Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to parainfluenza virus in serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause a variety of respiratory illnesses ranging from the common cold to pneumonia.

(b) *Classification.* Class I (general controls).

§ 866.3405 Poliovirus serological reagents.

(a) *Identification.* Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to poliovirus in serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis (polio) and provides epidemiological information on this disease. Poliomyelitis is an acute infectious disease which in its serious form affects the central nervous system resulting in atrophy (wasting away) of groups of muscles, ending in contraction and permanent deformity.

(b) *Classification.* Class I (general controls).

§ 866.3410 Proteus spp. (Weil-Felix) serological reagents.

(a) *Identification. Proteus* spp. (Weil-Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium *Proteus vulgaris* used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to rickettsia (virus-like bacteria) in serum. Test results aid in the diagnosis of diseases caused by bacteria belonging to the genus *Rickettsiae* and provide epidemiological information on these diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

(b) *Classification.* Class I (general controls).

§ 866.3415 Pseudomonas spp. serological reagents.

(a) *Identification. Pseudomonas* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identify *Pseudomonas* spp. from clinical specimens or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Pseudomonas*. *Pseudomonas aeruginosa* is a major cause of hospital-acquired infections, and has been associated with urinary tract infections, eye infections, burn and wound infections, blood poisoning, abscesses, and meningitis (inflammation of brain membranes). *Pseudomonas pseudomallei* causes melioidosis, a chronic pneumonia.

(b) *Classification.* Class II (performance standards).

§ 866.3460 Rabiesvirus immunofluorescent reagents.

(a) *Identification.* Rabiesvirus immunofluorescent reagents are devices that consist of rabiesvirus antisera conjugated with a fluorescent dye used to identify rabiesvirus in specimens taken from suspected rabid animals. The identification aids in the diagnosis of rabies in patients exposed by animal bites and provides epidemiological information on rabies. Rabies is an acute infectious disease of the central nervous system which, if undiagnosed, may be fatal. The disease is commonly transmitted to humans by a bite from a rabid animal.

(b) *Classification.* Class II (performance standards).

§ 866.3470 Reovirus serological reagents.

(a) *Identification.* Reovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to reovirus in serum. The identification aids in the diagnosis of reovirus infections and provides epidemiological information on diseases caused by these viruses. Reoviruses are thought to cause only mild respiratory and gastrointestinal illnesses.

(b) *Classification.* Class I (general controls).

§ 866.3480 Respiratory syncytial virus serological reagents.

(a) *Identification.* Respiratory syncytial virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to respirator syncytial virus in serum. Additionally, some of these reagents consist of

respiratory syncytial virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify respiratory syncytial viruses from clinical specimens or from tissue culture isolates derived from clinical specimens. The identification aids in diagnosis of respiratory syncytical virus infections and provides epidemiological information on diseases caused by these viruses. Respiratory syncytial viruses cause a number of respiratory tract infections, including the common cold, pharyngitis, and infantile bronchopneumonia.

(b) *Classification.* Class I (general controls).

§ 866.3490 Rhinovirus serological reagents.

(a) *Identification.* Rhinovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rhinovirus in serum. The identification aids in the diagnosis of rhinovirus infections and provides epidemiological information on diseases caused by these viruses. Rhinoviruses cause common colds.

(b) *Classification.* Class I (general controls).

§ 866.3500 Rickettsia serological reagents.

(a) *Identification.* Rickettsia serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rickettsia in serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens. The identification aids in the diagnosis of diseases caused by virus-like bacteria belonging to the genus *Rickettsiae* and provides epidemiological information on these diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

(b) *Classification.* Class I (general controls).

§ 866.3510 Rubella virus serological reagents.

(a) *Identification.* Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubella virus in serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

(b) *Classification.* Class III (premarket approval).

§ 866.3520 Rubeola (measles) virus serological reagents.

(a) *Identification.* Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to rubeola virus in serum. The identification aids in the diagnosis of measles and provides epidemiological information on the disease. Measles is an acute, highly infectious disease of the respiratory and reticuloendothelial tissues, particularly in children, characterized by a confluent and blotchy rash.

(b) *Classification.* Class I (general controls).

§ 866.3550 Salmonella spp. serological reagents.

(a) *Identification. Salmonella* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Salmonella* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Salmonella* spp. directly from clinical specimens or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus *Salmonella* and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever ("enteric fever"), severe diarrhea, and cramps.

(b) *Classification.* Class II (performance standards).

§ 866.3600 Schistosoma spp. serological reagents.

(a) *Identification. Schistosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Schistosoma* spp. in serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genus *Schistosoma.* Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer's itch), a skin disease marked by intense itching.

(b) *Classification.* Class I (general controls).

§ 866.3630 Serratia spp. serological reagents.

(a) *Identification. Serratia* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Serratia* spp. from cultured isolates. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Serratia* and provides epidemiological information on these diseases. *Serratia* spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.

(b) *Classification.* Class I (general controls).

§ 866.3660 Shigella spp. serological reagents.

(a) *Identification. Shigella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used in serological tests to identify *Shigella* spp. from cultured isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genus *Shigella* and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.

(b) *Classification.* Class II (performance standards).

§ 866.3680 Sporothrix schenckii serological reagents.

(a) *Identification. Sporothrix schenckii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Sporothrix schenckii* in serum. The identification aids in the diagnosis of sporothrichosis caused by a fungus belonging to the genus *Sporothrix* and provides epidemiological information on this disease. Sporothrichosis is a chronic tumorlike infection primarily of the skin.

(b) *Classification.* Class I (general controls).

§ 866.3700 Staphylococcus aureus serological reagents.

(a) *Identification. Staphylococcus aureus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates. The identification aids

in the diagnosis of disease caused by this bacterium belonging to the genus *Staphylococcus* and provides epidemiological information on these diseases. Certain strains of *Staphylococcus aureus* produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and causes destruction of the intestinal lining (gastroenteritis).

(b) *Classification.* Class I (general controls).

§ 866.3720 Streptococcus spp. exoenzyme reagents.

(a) *Identification. Streptococcus* spp. exoenzyme reagents are devices used to identify antibodies to *Streptococcus* spp. exoenzyme in serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(b) *Classification.* Class II (performance standards).

§ 866.3740 Streptococcus spp. serological reagents.

(a) *Identification. Streptococcus* spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(b) *Classification.* Class I (general controls).

§ 866.3780 Toxoplasma gondii serological reagents.

(a) *Identification. Toxoplasma gondii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Toxoplasma gondii* in serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Toxoplasma gondii* from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan *Toxoplasma gondii* and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

(b) *Classification.* Class II (performance standards).

§ 866.3820 Treponema pallidum nontreponemal test reagents.

(a) *Identification. Treponema pallidum* nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced from the reaction of treponema microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genus *Treponema* and provides epidemiological information on syphilis.

(b) *Classification.* Class II (performance standards).

§ 866.3830 Treponema pallidum treponemal test reagents.

(a) *Identification. Treponema pallidum* treponemal test reagents are devices that consist of the antigens, antisera and all control reagents (standardized reagents with which test results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA–ABS), the *Treponema pallidum* immobilization test (T.P.I.), and other treponemal tests used to identify antibodies to *Treponema pallidum* directly from infecting treponemal organisms in serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus *Treponema* and provides epidemiological information on syphilis.

(b) *Classification.* Class II (performance standards).

§ 866.3850 Trichinella spiralis serological reagents.

(a) *Identification. Trichinella spiralis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Trichinella spiralis* in serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus *Trichinella* and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(b) *Classification.* Class I (general controls).

§ 866.3870 Trypanosoma spp. serological reagents.

(a) *Identification. Trypanosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Trypanosoma* spp. in serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus *Trypanosoma.* Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

(b) *Classification.* Class I (general controls).

§ 866.3900 Varicella-zoster virus serological reagents.

(a) *Identification.* Varicella-zoster virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to varicella-zoster in serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

(b) *Classification.* Class II (performance standards).

§ 866.3930 Virbrio cholerae serological reagents.

(a) *Identification. Vibrio cholerae* serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis

of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(b) *Classification.* Class II (performance standards).

Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4100 Complement reagent.

(a) *Identification.* A complement reagent is a device that consists of complement, a naturally occurring serum protein from any warm-blooded animal such as guinea pigs, that may be included as a component part of serological test kits used in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 866.4500 Immunoelectrophoresis equipment.

(a) *Identification.* Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

(b) *Classification.* Class I (general controls).

§ 866.4520 Immunofluorometer equipment.

(a) *Identification.* Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.

(b) *Classification.* Class I (general controls).

§ 866.4540 Immunonephelometer equipment.

(a) *Identification.* Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody complexes. This generic type of device includes devices with various kinds of light sources, such as laser equipment.

(b) *Classification.* Class I (general controls).

§ 866.4600 Ouchterlony agar plate.

(a) *Identification.* An ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

(b) *Classification.* Class I (general controls).

§ 866.4800 Radial immunodiffusion plate.

(a) *Identification.* A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

§ 866.4830 Rocket immunoelectrophoresis equipment.

(a) *Identification.* Rocket immunoelectrophoresis equipment for clinical use is a device used to perform a specific test on proteins by using a procedure called rocket immunoelectrophoresis. In this procedure, an electric current causes the protein in solution to migrate through agar gel containing specific antisera. The protein precipitates with the antisera in a rocket-shaped pattern, giving the name to the device. The height of the peak (or the area under the peak) is proportional to the concentration of the protein.

(b) *Classification.* Class I (general controls).

§ 866.4900 Support gel.

(a) *Identification.* A support gel for clinical use is a device that consists of an agar or agarose preparation that is used while measuring various kinds of, or parts of, protein molecules by various immunochemical techniques, such as immunoelectrophoresis, immunodiffusion, or chromatography.

(b) *Classification.* Class I (general controls).

Subpart F—Immunological Test Systems

§ 866.5040 Albumin immunological test system.

(a) Identification. An albumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the albumin (a plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

(b) *Classification.* Class II (performance standards).

§ 866.5060 Prealbumin immunological test system.

(a) *Identification.* A prealbumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient's nutritional status.

(b) *Classification.* Class I (general controls).

§ 866.5065 Human allotypic marker immunological test system.

(a) *Identification.* A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochemical techniques the inherited human protein

allotypic markers (such as nGm, nA_2m, and Km allotypes) in serum and other body fluids. The identification may be used while studying population genetics.

(b) *Classification.* Class I (general controls).

§ 866.5080 Alpha-1-antichymotrypsin immunological test system.

(a) *Identification.* An *alpha*-1-antichymotrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques *alpha*-1-antichymotrypsin (a protein) in serum, other body fluids, and tissues. *Alpha*-1-antichymotrypsin helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.

(b) *Classification.* Class II (performance standards).

§ 866.5090 Antimitochondrial antibody immunological test system.

(a) *Identification.* An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body's own tissue), such as primary biliary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).

(b) *Classification.* Class II (performance standards).

§ 866.5100 Antinuclear antibody immunological test system.

(a) *Identification.* An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum, other body fluids, and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins). The measurements aid in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which antibodies attack the victim's own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjogren's syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

(b) *Classification.* Class II (performance standards).

§ 866.5110 Antiparietal antibody immunological test system.

(a) *Identification.* An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in serum and other body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin B_{12} to be absorbed by the body. The measurements aid in the diagnosis of vitamin B_{12} deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

(b) *Classification.* Class II (performance standards).

§ 866.5120 Antismooth muscle antibody immunological test system.

(a) *Identification.* An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).

(b) *Classification* Class II (performance standards).

§ 866.5130 Alpha-1-antitrypsin immunological test system.

(a) *Identification.* An *alpha*-1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-1-antitrypsin (a plasma protein) in serum, other body fluids, and tissues. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, *alpha*-1-antitrypsin deficiency has been associated with pulmonary emphysema.

(b) *Classification.* Class II (performance standards).

§ 866.5150 Bence-Jones proteins immunological test system.

(a) *Identification.* A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and plasma. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in urine and plasma, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

(b) *Classification.* Class II (performance standards).

§ 866.5160 Beta-globulin immunological test system.

(a) *Identification.* A *beta*-globulin immunological test system is a device that consists of reagents used to measure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids. *Beta*-globulin proteins include *beta*-lipoprotein, transferrin, glycoproteins, and complement, and are rarely associated with specific pathologic disorders.

(b) *Classification.* Class I (general controls).

§ 866.5170 Breast milk immunological test system.

(a) *Identification.* A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

(b) *Classification.* Class I (general controls).

§ 866.5200 Carbonic anhydrase B and C immunological test system.

(a) *Identification.* A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques specific carbonic anhydrase protein molecules in serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

(b) *Classification.* Class I (general controls).

§ 866.5210 Ceruloplasmin immunological test system.

(a) *Identification.* A ceruloplasmin immunological test system is a device

that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, other body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

(b) *Classification.* Class II (performance standards).

§ 866.5220 Cohn fraction II immunological test system.

(a) *Identification.* A Cohn fraction II immunological test system is a device that consists of the reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominantly of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques. Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

(b) *Classification.* Class I (general controls).

§ 866.5230 Colostrum immunological test system.

(a) *Identification.* A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

(b) *Classification.* Class I (general controls).

§ 866.5240 Complement components immunological test system.

(a) *Identification.* A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C1q, C_{1r}, C_{1s}, C_2, C_3, C_4, C_5, C_6, C_7, C_8, and C_9, in serum, other body fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurements of these proteins aids in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

(b) *Classification.* Class II (performance standards).

§ 866.5250 Complement C_1 inhibitor (inactivator) immunological test system.

(a) *Identification.* A complement C_1 inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C_1 inhibitor (a plasma protein) in serum. Complement C_1 inhibitor occurs normally in plasma and blocks the action of the C_1 component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C_1 inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

(b) *Classification.* Class II (performance standards).

§ 866.5260 Complement C_{3b} inactivator immunological test system.

(a) *Identification.* A complement C_{3b} inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C_{3b} inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C_{3b} inactivator aids in the diagnosis of inherited antibody dysfunction.

(b) *Classification.* Class II (performance standards).

§ 866.5270 C-reactive protein immunological test system.

(a) *Identification.* A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum and other body fluids. Measurement of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(b) *Classification.* Class II (performance standards).

§ 866.5320 Properdin factor B immunological test system.

(a) *Identification.* A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunochemical techniques properdin factor B in serum and other body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and other body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B aids in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermititis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.

(b) *Classification.* Class II (performance standards).

§ 866.5330 Factor XIII, A, S, immunological test system.

(a) *Identification.* A factor XIII, A, S, immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the factor XIII (a bloodclotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis and treatment of certain bleeding disorders resulting from a deficiency of this factor.

(b) *Classification.* Class I (general controls).

§ 866.5340 Ferritin immunological test system.

(a) *Identification.* A ferritin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ferritin (an iron-storing protein) in serum and other body fluids. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency amemia.

(b) *Classification.* Class II (performance standards).

§ 866.5350 Fibrinopeptide A immunological test system.

(a) *Identification.* A fibrinopeptide A immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the fibrinopeptide A (a blood-clotting factor) in plasma and other body fluids. Measurement of fibrinopeptide A may aid in the diagnosis and treatment of certain blood-clotting disorders.

(b) *Classification.* Class II (performance standards).

§ 866.5360 Cohn fraction IV immunological test system.

(a) *Identification.* A Cohn fraction IV immunological system is a device that consists of or measures that fraction of plasma proteins, predominantly *alpha-* and *beta*-globulins, used as a raw material for the production of pure *alpha-* or *beta*-globulins. Measurement of specific *alpha-* or *beta*-globulins aids in

the diagnosis of many diseases, such as Wilson's disease (an inherited disease affecting the liver and brain), Tangier's disease (absence of *alpha*-1-lipoprotein), malnutrition, iron deficiency anemia, red blood cell disorders, and kidney disease.

(b) *Classification.* Class I (general controls).

§ 866.5370 Cohn fraction V immunological test system.

(a) *Identification.* A Cohn fraction V immunological test system is a device that consists of or measures that fraction of plasma containing predominantly albumin (a plasma protein). This test aids in the diagnosis of diseases where albumin levels may be depressed, e.g., nephrosis (disease of the kidney), proteinuria (protein in the urine), gastroenteropathy (disease of the stomach and small intestine), rheumatoid arthritis, and viral hepatitis.

(b) *Classification.* Class I (general controls).

§ 866.5380 Free secretory component immunological test system.

(a) *Identification.* A free secretory component immunological test system is a device that consists of the reagents used to measure by immunochemical techniques free secretory component (normally a portion of the secretory IgA antibody molecule) in body fluids. Measurement of free secretory component (protein molecules) aids in the diagnosis or repetitive lung infections and other hypogammaglobulinemic conditions (low antibody levels).

(b) *Classification.* Class II (performance standards).

§ 866.5400 Alpha-globulin immunological test system.

(a) *Identificotion.* An *alpha*-globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-globulin (a serum protein) in serum and other body fluids. Measurement of *alpha*-globulin may aid in the diagnosis of inflammatory lesions, infections, severe burns, and a variety of other conditions.

(b) *Classification.* Class I (general controls).

§ 866.5420 Alpha-1-glycoproteins immunological test system.

(a) *Identification.* An *alpha*-1-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques *alpha*-1-glycoproteins (a group of plasma proteins found in the *alpha*-1 group when subjected to electrophoresis) in serum and other body fluids. Measurement of specific *alpha*-1-glycoproteins may aid in the diagnosis of collagen (connective tissue) disorders, tuberculosis, infections, extensive malignancy, and diabetes.

(b) *Classification.* Class I (general controls).

§ 866.5425 Alpha-2-glycoproteins immunological test system.

(a) *Identification.* An *alpha*-2-glycoproteins immunolgical test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-2-glycoproteins (a group of plasma proteins found in the *alpha*-2 group when subjected to electrophoresis) in serum and other body fluids. Measurement of *alpha*-2-glycoproteins aids in the diagnosis of some cancers and genetically inherited deficiencies of these plasma proteins.

(b) *Classification.* Class I (general controls).

§ 866.5430 Beta-2-glycoprotein I immunological test system.

(a) *Identification.* A *beta*-2-glycoprotein I immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *beta*-2-glycoprotein I (a serum protein) in serum and other body fluids. Measurement of *beta*-2-glycoprotein I aids in the diagnosis of an inherited deficiency of this serum protein.

(b) *Classification.* Class I (general controls).

§ 866.5440 Beta-2-glycoprotein III immunological test system.

(a) *Identification.* A *beta*-2-glycoprotein III immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *beta*-2-glycoprotein III (a serum protein) in serum and other body fluids. Measurement of *beta*-2-glycoprotein III aids in the diagnosis of an inherited deficiency of this serum protein and a variety of other conditions.

(b) *Classification.* Class I (general controls).

§ 866.5460 Haptoglobin immunological test system.

(a) *Identification.* A haptoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the haptoglobin (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

(b) *Classification.* Class II (performance standards).

§ 866.5470 Hemoglobin immunological test system.

(a) *Indentification.* A hemoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the different types of free hemoglobin (the oxygen-carrying pigment in red blood cells) in blood, urine, plasma, or other body fluids. Measurements of free hemoglobin aid in the diagnosis of various hematologic disorders, such as sickle cell anemia, Fanconi's anemia (a rare inherited disease), aplastic anemia (bone marrow does not produce enough blood cells), and leukemia (cancer of the blood-forming organs).

(b) *Classification.* Class II (performance standards).

§ 866.5490 Hemopexin immunological test system.

(a) *Indentification.* A hemopexin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the hemopexin (a serum protein that binds heme, a component of hemoglobin) in serum. Measurement of hemopexin aids in the diagnosis of various hematologic disorders, such as hemolytic anemia (anemia due to shortened in vivo survival of mature red blood cells and inability of the bone marrow to compensate for their decreased life span) and sickle cell anemia.

(b) *Classification.* Class II (performance standards).

§ 866.5500 Hypersensitivity pneumonitis immunological test system.

(a) *Identification.* A hypersensitivity pneumonitis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin antibodies in serum which react specifically with organic dust derived from fungal or animal protein sources. When these antibodies react with such dusts in the lung, immune complexes precipitate and trigger an inflammatory reaction (hypersensitivity pneumonitis). Measurement of these immunoglobulin G antibodies aids in the diagnosis of hypersensitivity pneumonitis and other allergic respiratory disorders.

(b) *Classification.* Class II (performance standards).

§ 866.5510 Immunoglobulins A, G, M, D, and E immunological test system.

(a) *Identification.* An immunoglobulins A, G, M, D, and E immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulins A, G, M, D, an E (serum antibodies) in serum. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

(b) *Classification.* Class II (performance standards).

§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fab fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fab antigen-binding fragment resulting from breakdown of immunoglobulin G antibodies in urine, serum, and other body fluids. Measurement of Fab fragments of immunoglobulin G aids in the diagnosis of lymphoproliferative disorders, such as multiple myeloma (tumor of bone marrow cells), Waldenstrom's macroglobulinemia (increased immunoglobulin production by the spleen and bone marrow cells), and lymphoma (tumor of the lymphoid tissues).

(b) *Classification.* Class II (performance standards).

§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fc fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fc (carbohydrate containing) fragment of immunoglobulin G (resulting from breakdown of immunoglobulin G antibodies) in urine, serum, and other body fluids. Measurement of immunoglobulin G Fc fragments aids in the diagnosis of plasma cell antibody-forming abnormalities, e.g., gamma heavy chain disease.

(b) *Classification.* Class II (performance standards).

§ 866.5540 Immunoglobulin G (Fd fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fd fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the amino terminal (antigen-binding) end (Fd fragment) of the heavy chain (a subunit) of the immunoglobulin antibody molecule in serum. Measurement of immunoglobulin G Fd fragments aids in the diagnosis of plasma antibody-forming cell abnormalities.

(b) *Classification.* Class I (general controls).

§ 866.5550 Immunoglobulin (light chain specific) immunological test system.

(a) *Identification.* An immunoglobulin (light chain specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques both kappa and lambda types of light chain portions of immunoglobulin molecules in serum, other body fluids, and tissues. In some disease states, an excess of light chains are produced by the antibody-forming cells. These free light chains, unassociated with gamma globulin molecules, can be found in a patient's body fluids and tissues. Measurement of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.

(b) *Classification.* Class II (performance standards).

§ 866.5560 Lactic dehydrogenase immunological test system.

(a) *Identification.* A lactic dehydrogenase immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the activity of the lactic dehydrogenase enzyme in serum. Increased levels of lactic dehydrogenase are found in a variety of conditions, including megaloblastic anemia (decrease in the number of mature red blood cells), myocardial infarction (heart disease), and some forms of leukemia (cancer of the blood-forming organs). However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.

(b) *Classification.* Class I (general controls).

§ 866.5570 Lactoferrin immunological test system.

(a) *Identification.* A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, breast milk, other body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

(b) *Classification.* Class I (general controls).

§ 866.5580 Alpha-1-lipoprotein immunological test system.

(a) *Identification.* An *alpha*-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-1-lipoprotein (high-density lipoprotein) in serum and plasma. Measurement of *alpha*-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

(b) *Classification.* Class II (performance standards).

§ 866.5590 Lipoprotein X immunological test system.

(a) *Identification.* A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

(b) *Classification.* Class I (general controls).

§ 866.5600 Low-density lipoprotein immunological test system.

(a) *Identification.* A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

(b) *Classification.* Class II (performance standards).

§ 866.5620 Alpha-2-macroglobulin immunological test system.

(a) *Identification.* An *alpha*-2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the *alpha*-2-macroglobulin (a serum protein) in plasma. Measurement of *alpha*-2-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.

(b) *Classification.* Class II (performance standards).

§ 866.5630 Beta-2-microglobulin immunological test system.

(a) *Identification.* A *beta*-2-microglobulin immunological test system is a device that consists of the

reagents used to measure by immunochemical techniques *beta*-2-microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of *beta*-2-microglobulin aids in the diagnosis of active rheumatoid arthritis and kidney disease.

(b) *Classification.* Class II (performance standards).

§ 886.5640 Infectious mononucleosis immunological test system.

(a) *Identification.* An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques heterophile antibodies frequently associated with infectious mononucleosis in serum, plasma, and other body fluids. Measurements of these antibodies aid in the diagnosis of infectious mononucleosis.

(b) *Classification.* Class II (performance standards).

§ 866.5660 Multiple autoantibodies immunological test system.

(a) *Identification.* A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in serum and other body fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (disease produced when the body's own tissues are injured by autoantibodies).

(b) *Classification.* Class II (performance standards).

§ 866.5680 Myoglobin immunological test system.

(a) *Identification.* A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of heart or renal disease.

(b) *Classification.* Class II (performance standards).

§ 866.5700 Whole human plasma or serum immunological test system.

(a) *Identification.* A whole human plasma or serum immunological test system is a device that consists of reagents used to measure by immunochemical techniques the proteins in plasma or serum. Measurements of proteins in plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

(b) *Classification.* Class I (general controls).

§ 866.5715 Plasminogen immunological test system.

(a) *Identification.* A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, other body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.

(b) *Classification.* Class I (general controls).

§ 866.5735 Prothrombin immunological test system.

(a) *Identification.* A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of blood-clotting disorders.

(b) *Classification.* Class I (general controls).

§ 866.5750 Radioallergosorbent (RAST) immunological test system.

(a) *Identification.* A radioallergosorbent immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodies which cause an allergic reaction) specific for a given allergen. Measurement of specific allergen antibodies may aid in the diagnosis of asthma, allergies, and other pulmonary disorders.

(b) *Classification.* Class II (performance standards).

§ 866.5765 Retinol-binding protein immunological test system.

(a) *Identification.* A retinol-binding protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the retinol-binding protein that binds and transports vitamin A in serum and urine. Measurement of this protein may aid in the diagnosis of kidney disease and in monitoring patients with kidney transplants.

(b) *Classification.* Class I (general controls).

§ 866.5775 Rheumatoid factor immunological test system.

(a) *Identification.* A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in serum, other body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

(b) *Classification.* Class II (performance standards).

§ 866.5800 Seminal fluid (sperm) immunological test system.

(a) *Identification.* A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results may be used as court evidence in alleged instances of rape and other sex-related crimes.

(b) *Classification.* Class I (general controls).

§ 866.5820 Systemic lupus erythematosus immunological test system.

(a) *Identification.* A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and other body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of SLE (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).

(b) *Classification.* Class II (performance standards).

§ 866.5860 Total spinal fluid immunological test system.

(a) *Identification.* A total spinal fluid immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of multiple sclerosis and other diseases of the nervous system.

(b) *Classification.* Class II (performance standards).

§ 866.5870 Thyroid autoantibody immunological test system.

(a) *Identification.* A thyroid autoantibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the thyroid autoantibodies

(antibodies produced against the body's own tissues). Measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic goiter (enlargement of thyroid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

(b) *Classification.* Class II (performance standards).

§ 866.5880 Transferrin immunological test system.

(a) *Identification.* A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and other body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders, such as iron deficiency anemia.

(b) *Classification.* Class II (performance standards).

§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.

(a) *Identification.* An inter-*alpha* trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter-*alpha* trypsin inhibitor (a protein) in serum and other body fluids. Measurement of inter-alpha trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification.* Class I (general controls).

Subpart G—Tumor Associated Antigen Immunological Test Systems

§ 866.6010 Carcinoembryonic antigen (CEA) immunological test system as an aid in the detection and management of cancer.

(a) *Identification.* A carcinoembryonic antigen (CEA) immunological test system as an aid in the detection and management of cancer is a device that consists of the reagents intended to measure by immunochemical techniques, such as enzyme immunoassay or radioimmunoassay, CEA in blood, plasma, other body fluids, and tissues. Measurement of CEA levels may aid in the detection and management of cancer.

(b) *Classification.* Class III (premarket approval) (transitional device).

The Food and Drug Administration has carefully analyzed the economic effects of this final rule in accordance with section 3(g)(1) of Executive Order 12291, and it has been determined that the final rule does not constitute a major rule as defined in section 1(b) of the Executive Order. Rules classifying devices into class I generally maintain the status quo: These devices are now subject to only the general controls provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, and 360j) and under the final rule, would remain subject only to such controls either in their entirety or with certain exemptions. Devices classified into class II would also remain subject only to the general controls provisions of the act unless and until an applicable performance standard were established. Similarly, devices classified into class III remain subject only to the general controls provisions of the act until an additional regulation is promulgated pursuant to section 515(b) of the act (21 U.S.C. 360e(b)) requiring that such devices have in effect approved applications for premarket approval. In accordance with section 501(f)(2)(B) of the act (21 U.S.C. 351(f)(2)(B)), devices classified by regulation into class III that were not previously considered new drugs may remain in commercial distribution without an approved premarket approval application for 30 months following the effective date of classification of the device into class III, or for 90 days following the promulgation of a regulation under section 515(b) of the act (21 U.S.C. 360e(b)), whichever occurs later. In sum, device classification rules are not major rules. The requirement for a regulatory flexibility analysis under the Regulatory Flexibility Act does not apply to this final rule because the proposed rules on which it is based were issued prior to January 1, 1981, and are therefore exempt.

Effective date. This regulation is effective December 9, 1982.

(Secs. 513, 520(l), 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 360j(1), 371(a)).)

Dated: October 14, 1982.

Mark Novitch,

Acting Commissioner of Food and Drugs.

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