Dated: March 31, 2000.

Linwood A. Watson, Jr.,

Acting Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 809 and 864

[Docket No. 97N–0135]

Hematology and Pathology Devices; Reclassification; Restricted Devices; OTC Test Sample Collection Systems for Drugs of Abuse Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying over-the-counter (OTC) test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) and exempting them from premarket notification (510(k)) and current good manufacturing practice (CGMP) requirements. FDA is also designating OTC test sample collection systems for drugs of abuse testing as restricted devices under the Federal Food, Drug, and Cosmetic Act (the act) and establishing restrictions intended to assure consumers that: The underlying laboratory test(s) are accurate and reliable; the laboratory performing the test(s) has adequate expertise and competency; and the product has adequate labeling and methods of communicating test results to consumers. Finally, FDA is adding a conforming amendment to the existing classification regulation for specimen transport and storage containers to clarify that it does not apply to specimen transport and storage containers that are part of an OTC test sample collection system for the purpose of testing for the presence of drugs of abuse or their metabolites in a laboratory.

DATES: This rule is effective April 9, 2001.

ADDRESSES: Comments on the burden estimates or on any other aspect of the information collection provisions should be sent to the Office of Device Evaluation (HFZ–440), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Steven Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 5, 1998 (63 FR 10792), FDA published a proposed rule to: (1) Reclassify OTC test sample collection systems for drugs of abuse testing from class III (premarket approval) into class I (general controls) and to exempt them from premarket notification (510(k)) and CGMP requirements; (2) to designate OTC test sample collection systems for drugs of abuse testing as restricted devices under the act; and (3) to establish restrictions intended to assure consumers that: The underlying laboratory test(s) are accurate and reliable, the laboratory performing the test(s) has adequate expertise and competency, and the product has adequate labeling and methods of communicating test results to consumers.

The proposed rule does not affect OTC tests for drugs of abuse that are performed in the home setting—i.e., the testing is performed in the home setting and the test results are read and interpreted directly by the consumer, without involvement or input from a health professional. These are referred to as ''point of care'' tests. When manufacturers or distributors market ''point of care'' tests, they are selling the consumers the actual test rather than a collection system that uses a laboratory to perform a test. Under these circumstances, FDA cannot determine whether the test is accurate and reliable without premarket review of the product. Accordingly, no changes are being proposed in FDA's current policy of reviewing ''point of care'' tests prior to marketing.

Interested persons were given until July 6, 1998, to submit written comments on the proposed rule. FDA received nine comments.

In the **Federal Register** of May 28, 1998 (63 FR 29174), FDA announced that on June 19, 1998, it would hold a public hearing on the proposed rule. FDA held that hearing as announced.

II. Response to Comments

FDA received nine comments on the proposed rule from individuals, manufacturers, and professional societies. The majority of comments supported FDA's proposed rule. A summary of the written comments as well as comments made at the public hearing and FDA's response is set forth in this section II.

A. General Comments

1. Six comments generally supported regulating OTC test sample collection systems for drugs of abuse as class I devices exempt from the premarket notification requirements. These comments asserted that deregulation of home drug test collection systems outlined in the proposed rule made drug testing more affordable and more accessible. These comments indicated support for the testing laboratory to provide a health care professional to communicate the proper interpretation of test results from the laboratory to the lay user.

B. Consumer Versus Workplace Test Kits

2. One comment stated that the rule fails to distinguish between test systems marketed directly to consumers and those intended for use in the workplace because the rule fails to take into account the additional safeguards that are present when drug testing is performed in the workplace. This comment went on to suggest that even if FDA concludes that it has jurisdiction to regulate all test systems, it should nevertheless exercise enforcement discretion with respect to drugs of abuse tests for the workplace because the workplace setting offers sufficient protections to ''ensure sample integrity and test accuracy.''

FDA disagrees with this comment. As explained in the proposed rule, FDA concluded that there should be consistency in its regulation of drugs of abuse test sample collection systems used in the home, workplace, insurance, and sports settings. Issues related to consumer use and quality are similar in all these settings, including concerns about sample integrity and test accuracy. FDA believes the need to provide assurance of test accuracy and reliability applies equally in all these areas.

However, FDA will continue to exercise its enforcement discretion with respect to the use of these products in the law enforcement setting because there are protections to ensure sample integrity and test accuracy that are not generally available in the home, workplace, insurance and sports settings. The additional protections include the use of rules of evidence in judicial proceedings and the representation of the accused (i.e., the person being tested) through the judicial process.

C. FDA Oversight

3. One comment expressed concern over the proposal to exempt manufacturers from the 510(k) process and suggested the need for data to be presented to demonstrate that each analyte is unaffected by storage and transport, i.e., stored and not altered or interfered with. This comment stated that there is a potential for materials in collection cups to interfere with an accurate test result.

Mail-in drug testing is practiced routinely in many settings. The materials and methods for shipping urine are in widespread use for drugs of abuse testing in Substance Abuse and Mental Health Service Administration (SAMHSA) or equivalent certified laboratories. Data submitted to the FDA have shown drugs of abuse test specimens to be stable when shipped in accordance with the requirements of SAMHSA or equivalent certified laboratories. Although FDA has exempted the OTC test sample collection systems for drugs of abuse testing from premarket review, all of these systems will be required to use screening tests that have been approved, cleared, or otherwise recognized by FDA as accurate and reliable for testing. The final rule further requires manufacturers and suppliers to comply with medical device reporting requirements (21 CFR part 803) and report adverse events that may have been due to the OTC collection containers. FDA believes these general controls, without premarket notification, provide reasonable assurance that these products will be used safely and effectively.

D. In-House Tests

4. One comment stated that FDA's proposed rule would impose on clinical laboratories using in-house (home brew) assays additional and burdensome requirements that are unnecessary under the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88).

FDA disagrees with this comment. In order for products to be used OTC, they must be cleared by FDA. The agency believes that the FDA requirements will be complementary to those of CLIA and will address issues related to device safety and effectiveness outside the usual CLIA review program. CLIA requirements focus on the proficiency of the laboratories performing tests and the new regulation recognizes the need for such laboratories to have adequate expertise.

5. One comment stated that the rule unfairly discriminates against companies using screening assays for which there are no FDA-cleared screening tests, thereby imposing premarket approval requirements for the test system.

FDA does not agree that the rule discriminates unfairly. This rule is designed to ensure that there is a level playing field and that all manufacturers marketing home test collection systems use testing methods that have been approved, cleared, or otherwise recognized by FDA as accurate and reliable.

6. One comment voiced opposition to the FDA proposal to require companies marketing drugs-of-abuse test systems that employ in-house screening tests to establish validity of these tests with FDA before marketing the test system. This comment stated that FDA lacks jurisdiction to regulate the provision of laboratory testing services by clinical laboratories.

The agency believes that in-house (home brew) laboratory tests are medical devices subject to regulation by FDA. FDA considers clinical laboratories that develop such tests to be acting as manufacturers. In a recent regulation to classify/reclassify analyte specific reagents FDA stated its desire to regulate in-house developed tests in a way that would not inhibit the development of such tests or diminish the contribution they make to public health (62 FR 62243 at 62249, November 21, 1997). However, in instances where these tests are part of systems intended for lay users, the agency believes that the additional oversight provided by agency premarket review of the test is necessary to ensure the safety and effectiveness of the device.

7. One comment asked if the drugs of abuse testing required under the proposed rule would be covered under CLIA requirements for high complexity testing.

The answer is yes. Because the confirmation testing of presumptive positives is designated as a high complexity test under CLIA, CLIA standards for high complexity testing would apply.

E. Laboratory Standards

8. Three comments emphasized the importance of confirmation of presumptive results and suggested that this be a mandatory part of OTC test sample collection systems.

FDA agrees with these comments. The rule specifically requires that the laboratory performing the test shall have adequate capability to reliably perform the necessary screening and confirmatory testing.

9. One comment suggested that laboratories testing any drugs of abuse or their metabolites not covered by SAMHSA should meet standards of organizations with deemed accreditation status such as College of American Pathologists (CAP).

FDA agrees with this comment. The agency's rule clearly stated that the laboratory performing the test shall have, and shall be recognized as having, adequate capability to reliably perform the necessary screening and confirmatory tests. Such recognition would include CAP accreditation.

10. One comment expressed concern that a high complexity CLIA certified laboratory (e.g., toxicology laboratory) would not meet the SAMHSA standards that are required for laboratories performing Federal workplace drug-testing. The comment stated that OTC products relying on non-SAMHSA certified laboratories would lower the standards of competency for drugs of abuse testing.

FDA recognizes that there are differences in toxicology laboratory certification programs. However, the agency believes that the standards established by the rule, as proposed, are appropriate, because they ensure an acceptable level of testing performance. As discussed previously, the rule requires the laboratory to be recognized as being able to reliably perform screening and confirmatory testing, including the capability to check biological specimens for possible adulteration. FDA believes that such recognition of capability and good laboratory practice may be demonstrated in a number of ways including SAMHSA certification, CAP accreditation, and CLIA high complexity designation.

11. One comment suggested FDA consider allowing laboratories to report the lowest concentration of drug they are able to detect in order to encourage improvement in the sensitivity of the system.

FDA has not specified concentration levels for drugs being tested in these systems. The agency expects sponsors to label their products to reflect the chosen performance levels using appropriate cut-off points.

12. One comment suggested it would be helpful to clarify whether the screening and confirmation testing must be performed at the same physical site in the same laboratory.

The regulation requires the laboratory performing the test to have adequate capability to reliably perform the necessary screening and confirmatory testing. While the expectation is that this testing usually will be performed at

a single site, the rule does not preclude a laboratory operating as a single entity from housing different analytical functions at different sites. The rule also does not prevent laboratories from making contractual agreements to acquire or share analytical resources so long as the other laboratory meets the necessary standards.

13. One comment noted that laboratory customers are often not aware of the limits of the SAMHSA coverage and suggested that the regulation should make clear the actual jurisdiction of the SAMHSA standards.

FDA agrees that this is useful information. The dissemination of this information, however, falls outside of the scope of this rule.

F. FDA Labeling

14. One comment suggested that the guidance document that FDA intends to develop should encourage manufacturers to list all drugs that will not be covered under the test.

The agency does not agree that an exhaustive listing of drugs not being tested is reasonable or user-friendly. FDA believes the labeling for the test should clearly indicate: (1) What drugs are being tested, (2) what limitations exist, and (3) examples of these limitations. For example, a label may include the information that strong oxidizing agents such as bleach can oxidize drug analytes and explain that, if a sample is suspected of being adulterated, a new sample must be obtained. The agency intends to include examples of appropriate labeling in its guidance.

15. One comment suggested that test labeling should explicitly offer guidance on how to contact a resource for test interpretation as well as identifying resources for counseling and treatment.

FDA agrees with this comment. The regulation does require labeling of these products to include adequate instructions on how to obtain test results from a person who can explain their meaning, including the probability of false positive and false negative results, as well as how to contact a trained health professional if additional information on interpretation of test results from the laboratory or followup counseling is desired. In the **Federal Register** of December 21, 1999 (64 FR 71461), FDA announced the availability of a draft guidance document entitled ''Draft Guidance on Labeling for Over-the-Counter Sample Collection Systems for Drugs of Abuse Testing.'' The draft guidance provides to manufacturers FDA's thinking on ways to comply with the labeling requirements in this rule. For example, it states the labeling should include advice on contacting a physician for options for identifying and/or treating substance use and abuse problems, and should include a statement on how to obtain information for talking to children about drug use and abuse. FDA intends to finalize the guidance before the effective date of this final rule.

16. One comment stated that training of users is essential in collection of these specimens.

FDA agrees that this is an important issue. Guidance on labeling of home use devices is available both from NCCLS (GP–14–A ''Labeling for Home Use In-Vitro Products'') and from FDA (''Write It Right'' and ''Points to Consider Regarding Labeling and Premarket Submissions for Home Use In-Vitro Diagnostic Devices''). These guidances can help manufacturers to develop high quality instruction manuals for users of medical devices in the home that are easy to read, understand, and follow. The manufacturers also can enlist the aid of health care professionals and home medical equipment suppliers to stress the importance of the manual to the lay users.

G. Hair Testing

17. One comment objected that OTC drugs of abuse test kits are not medical devices under section 201(h) of the act (21 U.S.C. 321(h)). The comment argued that FDA lacks jurisdiction to regulate test kits that detect drugs of abuse in hair because they are not considered devices for medical diagnosis and treatment. This comment stated that hair analysis provides no information concerning intoxication or addiction.

FDA disagrees with the comment. The definition of device as set forth in section 201(h) of the act includes the following:

> The term ''device'' * * * means an instrument, apparatus, implement, machine, contrivance, implant, *in vitro reagent*, or other similar or related article, *including any component, part, or accessory*, which is— * * * (2) *intended for use in the diagnosis of disease or other conditions* * * * [emphasis added]

The test for evidence of drug abuse is intended to provide information about a condition, namely, whether drugs of abuse are being used or have been used by the subject. In addition, such information can be used to diagnose other conditions or diseases, including addiction or intoxication, and may also be used to eliminate such conditions as part of a diagnosis of an underlying disease.

18. One comment endorsed the use of hair testing and indicated that it provided a valuable extension of the window for testing for hard drugs of abuse in children.

FDA agrees that hair testing may be a valuable test. To date the agency has not received a premarket submission for such a test. The agency does believe that these tests should be subject to appropriate premarket scientific review. The review standards applied to these tests will depend on the claims the manufacturer makes. FDA is committed to working with companies to develop appropriate study design and generate data sets to help characterize performance and establish labeling for these products that would be of benefit to lay users.

19. One comment said that, if FDA requires agency premarket review of tests for hair or other nonurine specimens, the agency cannot impose a higher regulatory burden on hair-based testing than on urine-based testing.

FDA is not imposing a higher regulatory burden on hair-based testing than on urine-based testing. This rule applies to the OTC test sample collection system, not the test itself, and applies equally, whether the sample collected is hair or urine. The regulatory burden imposed on a device is contingent upon the intended use, indications for use, and technological characteristics of the individual device.

20. One comment suggested FDA's proposal is irrational in requiring premarket notification for a specimen collection container for hair while exempting from premarket notification urine specimen collection containers and other specimen collection containers that are used in conjunction with screening tests previously approved, cleared, or otherwise recognized by FDA.

The comment appears to misunderstand the rule. FDA will treat all collection containers used in these products in an equivalent manner. Whenever such containers are part of a system that uses a cleared, approved, or recognized test performed in an appropriately regulated laboratory, the collection container will be exempt from any premarket review.

III. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The Office of Management and Budget (OMB) has determined that this final rule is a significant regulatory action subject to review under the Executive Order.

The reclassification of OTC test sample collection systems for drugs of abuse testing (class III into class I exempt) is reasonably expected to provide economic benefit to the health care system, individual consumers, and regulated industry. At this time, only a very limited number of OTC products for drugs of abuse testing (without professional assistance) are available to parents. By greatly increasing access, this reclassification may provide benefits to families. First, testing may serve as a deterrent to drug use and prevent the initial experimentation with drugs of abuse by children. Next, when drugs are being used, increased access to testing may allow for earlier detection of this condition and provide opportunities for earlier intervention and treatment. Early intervention and treatment has the potential to be more successful. Finally, products for drugs of abuse testing marketed to parents may be used to monitor children already undergoing treatment for drug use, deterring or at least detecting recidivism, which is currently estimated at 30 to 50 percent. In addition, the regulation, which regulates such testing systems consistently in home, workplace, athletic, and insurance settings, will help ensure all consumers that the product produces accurate and reliable results.

FDA cannot quantify the beneficial effect on the public health that will result from easier access to these tests. Nevertheless, the agency finds that the product has significant potential to reduce drug use. As the nation's economic costs of drug abuse are staggering, estimated at up to $110 billion in 1995, the potential benefit from even a modest reduction would be substantial.

Moreover, the cost to industry will fall. Under the current classification, OTC test sample collection systems for drugs of abuse testing are class III medical devices requiring a premarket approval application (PMA). FDA has found that the median development cost for a PMA ranges from $0.5 to $ 1 million. Reclassifying these devices as class I devices exempt from premarket notification, which do not undergo premarket review, means that neither new sponsors nor product purchasers will incur these costs. Consequently, FDA expects the rule to reduce regulatory costs at the same time that it decreases the economic burdens of drug abuse.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class I will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act (21 U.S.C. 360e). Because this rule will not require premarket review of the vast majority of OTC test sample collection systems for drugs of abuse testing, the agency certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of $100 million or more in any one year on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of these information collection provisions is given in this section V with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: OTC Test Sample Collection Systems for Drugs of Abuse Testing.

Description: The final rule amends the labeling requirements for certain in vitro diagnostic products to require that manufacturers of OTC test sample collection systems for drugs of abuse testing provide certain information to consumers for the proper use of the test sample collection system and for interpreting the results. The purpose of the regulation is to ensure that lay persons collecting samples for testing have adequate instructions for sample collection and handling and for receiving and understanding the test results reported by laboratories performing the analyses.

Description of Respondents: Businesses and other for-profit organizations.

There were no comments on the paperwork provisions in the proposed rule.

TABLE1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
809.10(f)	20	1	20	100	2,000

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Individuals and organizations may submit comments on these burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the Office of Device Evaluation (HFZ–440), Center for Devices and Radiological Health, Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850.

The information collection provisions in this final rule have been approved under OMB control number 0910–0368. This approval expires April 30, 2001. An agency may not conduct or sponsor,

and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects

21 CFR Part 809

Labeling, Medical devices.

21 CFR Part 864

Biologics, Blood, Laboratories, Medical devices, Packaging and containers.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 809 and 864 are amended as follows:

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

1. The authority citation for 21 CFR part 809 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 355, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

2. Section 809.10 is amended by adding paragraph (f) to read as follows:

§ 809.10 Labeling for in vitro diagnostic products.

* * * * *

(f) The labeling for over-the-counter (OTC) test sample collection systems for drugs of abuse testing shall bear the following information in language appropriate for the intended users:

(1) Adequate instructions for specimen collection and handling, and for preparation and mailing of the specimen to the laboratory for testing.

(2) An identification system to ensure that specimens are not mixed up or otherwise misidentified at the laboratory, and that user anonymity is maintained.

(3) The intended use or uses of the product, including what drugs are to be identified in the specimen, a quantitative description of the performance characteristics for those drugs (e.g., sensitivity and specificity) in terms understandable to lay users, and the detection period.

(4) A statement that confirmatory testing will be conducted on all samples that initially test positive.

(5) A statement of warnings or precautions for users as established in the regulations contained in 16 CFR part 1500 and any other warnings appropriate to the hazard presented by the product.

(6) Adequate instructions on how to obtain test results from a person who can explain their meaning, including the probability of false positive and false negative results, as well as how to contact a trained health professional if additional information on interpretation of test results from the laboratory or followup counseling is desired.

(7) Name and place of business of the manufacturer, packer, or distributor.

3. Section 809.40 is added to subpart C to read as follows:

§ 809.40 Restrictions on the sale, distribution, and use of OTC test sample collection systems for drugs of abuse testing.

(a) Over-the-counter (OTC) test sample collection systems for drugs of abuse testing (§ 864.3260 of this chapter) are restricted devices under section 520(e) of the Act subject to the restrictions set forth in this section.

(b) Sample testing shall be performed in a laboratory using screening tests that have been approved, cleared, or otherwise recognized by the Food and Drug Administration as accurate and reliable for the testing of such specimens for identifying drugs of abuse or their metabolites.

(c) The laboratory performing the test(s) shall have, and shall be recognized as having, adequate capability to reliably perform the necessary screening and confirmatory tests, including adequate capability to perform integrity checks of the biological specimens for possible adulteration.

(d) All OTC test sample collection systems for drugs of abuse testing shall be labeled in accordance with § 809.10(f) and shall provide an adequate system to communicate the proper interpretation of test results from the laboratory to the lay purchaser.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

4. The authority citation for 21 CFR part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

5. Section 864.3250 is amended in paragraph (a) by adding a sentence to the end of the paragraph to read as follows:

§ 864.3250 Specimen transport and storage containers.

(a) * * * This section does not apply to specimen transport and storage containers that are intended for use as part of an over-the-counter test sample collection system for drugs of abuse testing.

* * * * *

6. Section 864.3260 is added to subpart D to read as follows:

§ 864.3260 OTC test sample collection systems for drugs of abuse testing.

(a) *Identification.* An over-the-counter (OTC) test sample collection system for drugs of abuse testing is a device intended to: Collect biological specimens (such as hair, urine, sweat, or saliva), outside of a medical setting and not on order of a health care professional (e.g., in the home, insurance, sports, or workplace setting); maintain the integrity of such specimens during storage and transport in order that the matter contained therein can be tested in a laboratory for the presence of drugs of abuse or their metabolites; and provide access to test results and counseling. This section does not apply to collection, transport, or laboratory testing of biological specimens for the presence of drugs of abuse or their metabolites that is performed to develop evidence for law enforcement purposes.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification requirements in part 807, subpart E of this chapter subject to the limitations in § 864.9 if it is sold, distributed, and used in accordance with the restrictions set forth in § 809.40 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.198 of this chapter with respect to complaint files.

Dated: December 22, 1999.

Jane E. Henney,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 00P–1209]

Medical Devices; Laser Fluorescence Caries Detection Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the laser fluorescence caries detection device into class II (special controls). The special controls that will apply to this device are set forth below. The