guarantees), measured at the issuer's most recent balance sheet date; or

(iii) 15% of the outstanding amount of the class of securities being offered and sold in reliance on this section, measured at the issuer's most recent balance sheet date.

(3) Rules for calculating prices and amounts—(i) Aggregate sales price. The term aggregate sales price means the sum of all cash, property, notes, cancellation of debt or other consideration received or to be received by the issuer for the sale of the securities. Non-cash consideration must be valued by reference to *bona fide* sales of that consideration made within a reasonable time or, in the absence of such sales, on the fair value as determined by an accepted standard. The value of services exchanged for securities issued to employees, as well as to consultants and advisors, should be included in the aggregate sales price.

(ii) Derivative securities. In calculating outstanding securities for purposes of paragraph (d)(2)(iii) of this section, treat the securities underlying all currently exercisable or convertible options, warrants, rights or other securities, other than those issued under this section, as outstanding. In calculating the amount of securities sold for purposes of paragraph (d)(1) of this section, count the amount of securities that would be acquired upon exercise or conversion in connection with sales of options, warrants, rights or other exercisable or convertible securities.

(iii) Other exemptions. Amounts of securities sold in reliance on this section do not affect amounts that may be sold in reliance on other exemptions, and amounts of securities sold in reliance on other exemptions do not affect amounts that may be sold in reliance on this section.

(e) Disclosure that must be provided—The issuer must deliver the following disclosure to investors a reasonable period of time prior to the date of sale:

(1) A copy of the compensatory benefit plan or the contract, as applicable;

(2) If the plan is subject to the Employee Retirement

Income Security Act of 1974 (''ERISA'') (29 U.S.C. 1104–1107), a copy of the summary plan description required by ERISA;

(3) If the plan is not subject to ERISA, a summary of the material terms of the plan;

(4) Information about the risks associated with investment in the securities sold pursuant to the compensatory benefit plan or compensation contract; and

(5) Financial statements required to be furnished by Part F/S of Form 1–A (Regulation A Offering Statement) (§ 239.90 of this chapter). Such financial statements must be as of a date no more than 180 days prior to the sale of securities in reliance on this section. If the issuer is relying on § 230.701(d)(2)(ii) to use its parent's total assets to determine the amount of securities that may be sold, the parent's financial statements must be delivered. If the parent is subject to the reporting requirements of section 13 or 15(d) of the Exchange Act (15 U.S.C. 78m or 78o(d)), the financial statements of the parent required by Rule 10–01 of Regulation S–X (§ 210.10–01 of this chapter) and Item 310 of Regulation S–B (§ 228.310 of this chapter), as applicable, must be delivered.

(6) If the sale involves a stock option or other exercisable or convertible security, the issuer must deliver disclosure a reasonable period of time prior to the date of exercise or conversion. For deferred compensation or similar plans, the issuer must deliver disclosure to investors a reasonable period of time prior to the date the irrevocable election to defer is made.

(f) No integration with other offerings. Offers and sales exempt under this section are deemed to be a part of a single, discrete offering and are not subject to integration with any other offers or sales, whether registered under the Act or otherwise exempt from the registration requirements of the Act.

(g) Resale limitations—(1) Securities issued pursuant to this section are deemed to be ''restricted securities'' as defined in § 230.144.

(2) Resales of securities issued pursuant to this section must be in compliance with the registration requirements of the Act or an exemption therefrom.

(3) Ninety days after the issuer becomes subject to the reporting requirements of section 13 or 15(d) of the Exchange Act (15 U.S.C. 78m or 78o(d)), securities issued pursuant to this section may be resold by persons who are not affiliates (as defined in § 230.144) in reliance on § 230.144 without compliance with paragraphs (c), (d), (e) and (h) of § 230.144, and by affiliates without compliance with paragraph (d) of § 230.144.

By the Commission.

Dated: February 27, 1998.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–5728 Filed 3–4–98; 8:45 am]

BILLING CODE 8010–01–P

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify over-the-counter (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 the premarket notification (510(k)) and current good manufacturing practice (CGMP) requirements. FDA is also proposing to designate OTC test sample collection systems for drugs of abuse testing as restricted devices under the Federal Food, Drug, and Cosmetic Act (the act), and 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. Finally, FDA is proposing 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: Written comments on the proposed rule by July 6, 1998. FDA proposes that any final regulation based on this proposal become effective 1 year after its date of publication in the **Federal Register**.

Written comments on the information collection requirements should be submitted by April 6, 1998.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

Submit written comments on the information collection requirements to the Office of Information and Regulatory

Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

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 recent years, there has been increasing interest in extending testing for drugs of abuse to the home setting and test sample collection systems for such purposes have been developed and marketed. Test sample collection systems that have been developed for use in the home setting have generally consisted of: A collection cup or other container for collecting a specimen; directions for use; packaging for storage or mailing; access to a laboratory testing service; and access to test results. The consumer collects a specimen (such as urine) from the body and mails it to a laboratory, which performs the actual testing for the drugs or their metabolites. The specimen usually is identified by a code number, which maintains confidentiality and protects against mix-ups. The test results are communicated back to the consumer. Because these test systems for OTC use were not in commercial distribution prior to enactment of the 1976 Medical Device Amendments, they are new devices that are automatically classified by statute into class III. FDA's proposal would reclassify these test sample collection systems into class I and subject them to less stringent controls.

A specimen transport and storage *container* is one component of an OTC drugs of abuse test sample collection system. Under 21 CFR 864.3250, a specimen transport and storage container is identified as a device intended to contain biological specimens, body waste, or body exudate during storage and transport in order that the matter contained therein can be destroyed or used effectively for diagnostic examination. The container is classified as class I under the regulation and, if intended for professional use, it has been exempt from the premarket notification requirements. If the container is intended for OTC use, i.e., a specimen from the body is collected outside of a medical setting (e.g., at home) and mailed to a laboratory for testing, the agency has historically required the submission of a premarket notification (510(k)) or premarket approval application (PMA). FDA's proposal would amend this identification to recognize that a specimen collection container that is intended to be part of an OTC test sample collection system for drugs of abuse should be regulated as part of that system and subject to less stringent controls.

The appropriate level of regulation for OTC test sample collection systems for drugs of abuse testing has been the subject of considerable public discussion. Two public hearings on the issue have been held by the House Subcommittee on Oversight and Investigations—the first on September 26, 1996, and the second on February 6, 1997. Critics at the September hearing argued that the agency's categorization of these test systems as class III medical devices is unnecessarily stringent and that there are benefits to making these products available to parents. Another criticism raised at that time was the inconsistency between the agency's regulation of drugs of abuse test systems for use in the home setting and its exercise of enforcement discretion with respect to the same or similar products used in the workplace, insurance, sports, and law enforcement settings.

After considering these concerns, the agency committed to reevaluate its policy to determine the appropriate level of regulation for home drugs of abuse test sample collection systems. While the policy was being reevaluated, FDA established an interim policy on the availability of home test sample collection systems sold directly to parents for drugs of abuse testing. The interim policy, dated October 3, 1996, set forth FDA's intention to exercise its enforcement discretion and not take regulatory action against persons distributing home drugs of abuse test sample collection systems so long as three criteria were met: (1) The laboratory conducting the testing used an FDA-cleared test; (2) the testing laboratory met standards set by the Substance Abuse and Mental Health Services Administration (SAMHSA) or equivalent standards for performing such testing; and (3) the product had accurate labeling (Ref. 1).

In reevaluating the policy on home drugs of abuse test sample collection systems, the agency reached a number of conclusions, as described in testimony before the House Subcommittee on Oversight and Investigations on February 6, 1997 (Ref. 2).

The first conclusion was that these test sample collection systems must be accurate and reliable. Because there currently are more than 200 FDA-cleared urine tests for detecting drugs of abuse and hundreds of laboratories believed to be capable of conducting this testing, the agency concluded that accurate and reliable testing is readily available.

The second conclusion was that there is a public benefit in having drugs of abuse test sample collection systems available for use in the home setting. Thus, the agency should reduce the difficulty of getting these products onto the market for such use. FDA believes it can accomplish this and still ensure that consumers get accurate and reliable answers from these test sample collection systems.

The third conclusion related to the degree of consistency needed between FDA's regulation of drugs of abuse test sample collection systems for use in the home setting and the regulation of such systems used in the workplace, insurance, and sports settings. Because the same concerns about getting an accurate and reliable answer apply in all of these settings, FDA concluded that the same rules should govern drugs of abuse test sample collection systems used in all of these nonprofessional settings.

Fourth, FDA concluded that the agency should continue to exercise its enforcement discretion with respect to testing for drugs of abuse in the law enforcement setting because there are other protections to ensure sample integrity and test accuracy that are not 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.

Finally, FDA concluded that it is important to give the marketplace time to adjust to any changes in regulatory approach.Therefore, FDA would propose to provide an adequate transition period for implementing its proposed policy.

FDA's testimony also noted that, on January 21, 1997, the agency approved the first PMA for an OTC test sample collection system for drugs of abuse. The product is marketed as Dr. Brown's Home Drug Testing System, made by Personal Health and Hygiene Inc. (Ref. 3). The product met all the criteria in FDA's interim policy of October 3, 1996.

FDA recognizes the importance of empowering parents to address the abuse of drugs by their children through access to products that can detect drug use. FDA also recognizes that it has a statutory obligation to assure parents of the accuracy and reliability of such products for home use. In light of these

conclusions, FDA is proposing a new approach for the regulation of OTC test sample collection systems for drugs of abuse.

II. Proposal for Regulating OTC Test Sample Collection Systems for Drugs of Abuse

Based on FDA's knowledge of these products, the accuracy and reliability of the tests currently available, and the low potential risk to health, FDA believes that use of sample collection systems for drugs of abuse testing outside of a medical setting does not raise new issues that warrant premarket approval. Accordingly, FDA is proposing to reclassify OTC test sample collection systems for drugs of abuse testing from class III into class I, the least restrictive of the three regulatory classes, and is proposing to exempt such systems from the requirements of premarket review subject to restrictions established in accordance with section 520(e) of the act (21 U.S.C. 360j(e)). Under the proposed rule, three restrictions would be established, as follows.

First, the laboratory test(s) incorporated in these systems would be required to have been cleared, approved, or otherwise recognized by FDA as accurate and reliable for laboratory use. This would ensure that drugs of abuse test sample collection systems that are sold to consumers are accurate and reliable. Under the proposed rule, FDA would be able to utilize the expertise of another Federal agency (e.g., SAMHSA) when that agency reaches a formal determination regarding the suitability of a particular laboratory test or method for identifying the presence of drugs of abuse or their metabolites.

Because FDA has already cleared more than 200 laboratory urine tests to detect drugs of abuse, companies would have a relatively easy route to marketing OTC drugs of abuse urine test sample collection systems. Once this new policy is implemented, however, companies seeking to market a system that uses any test that has not been recognized by FDA (e.g., tests using hair as the test specimen) would need to establish the validity of the test with FDA prior to marketing. FDA's proposed transition period would allow ample time for companies to make this showing.

The second proposed criterion for ensuring that drugs of abuse test sample collection systems are accurate and reliable for use in a nonprofessional setting is that the laboratory performing the underlying test(s) must be able to reliably perform the necessary screening and confirmatory tests. This would ensure that testing is performed by individuals with appropriate levels of training, knowledge, and proficiency; that confirmatory testing is systematically performed on presumptively positive samples prior to issuance of the test results; and that assistance with interpretation of the test results and followup counseling is available to the consumer by a trained health professional, if requested. FDA plans to rely on existing laboratory certification programs to identify those individual laboratories that meet this criterion.

FDA believes that this criterion can also be readily met. There are 70 laboratories certified by SAMHSA that would clearly meet these requirements (Ref. 4). In addition, FDA believes that high-complexity laboratories under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that are certified in the area of toxicology by the Health Care Financing Administration, the College of American Pathologists, or other organizations with deemed status in the area of toxicology accreditation, would also have the appropriate types of controls (Ref. 5). FDA solicits comment on whether these or other existing certification programs would be adequate to establish competency of testing laboratories for these purposes. FDA also solicits comments on whether mandatory confirmatory testing of presumptive positive samples is an appropriate restriction on such OTC test sample collection systems.

The third proposed criterion to ensure that drugs of abuse test sample collection systems are accurate and reliable for use in a nonprofessional setting is that samples be adequately identified to avoid mix-ups and the test sample collection system be accurately labeled so that consumers can readily use it. This would ensure that the test sample collection system is accompanied by adequate directions that enable the lay person to: (a) Understand the purpose of the test—i.e., what drugs are and are not to be identified in the specimen; (b) understand the detection period; and (c) properly collect the test specimen and mail it to the laboratory. The labeling also would provide information regarding interpretation of test results (e.g., false positives and false negatives) and how the consumer can contact a qualified health professional for assistance in that interpretation, and obtain professional counseling, if needed.

To help manufacturers meet this criterion, FDA plans to develop guidance on issues such as how to label the test sample collection system so that the consumer can understand the test results and how to ensure that the specimen and the container remain properly identified and intact during mailing to the laboratory. The guidance also would address methods for providing consumers with adequate professional assistance in interpreting/understanding test results and providing counseling referrals, if needed. FDA believes this third criterion would also be relatively easy to meet.

FDA believes that these three criteria are needed to ensure that drugs of abuse test sample collection systems are accurate and reliable for use in a nonprofessional setting—e.g., in the home, insurance, sports, or workplace setting. Without these restrictions, FDA believes that there cannot otherwise be reasonable assurance of the safety and effectiveness of OTC test sample collection systems for drugs of abuse testing. FDA is interested in comments from other agencies concerned with drug testing about the impact of the agency's proposal.

If the above criteria are met, FDA proposes to allow companies to market OTC drugs of abuse test sample collection systems without first obtaining premarket approval or clearance, i.e., if the criteria are met, manufacturers or distributors of the product could go directly to market. FDA believes that these three criteria are clear and that manufacturers or distributors of OTC drugs of abuse test sample collection systems can readily determine for themselves if those criteria are met. Should a manufacturer or distributor market such a product without meeting these restrictions, the product would be adulterated under section 502(q) of the act (21 U.S.C. 352) and subject to enforcement action. FDA solicits comments on whether 510(k)'s for these devices should be required, rather than the 510(k) exempt status that is being proposed.

Under FDA's proposal, FDA would regulate drugs of abuse test sample collection systems used in the insurance, workplace, and sports settings in a consistent manner with those systems that are used in the home, because the need for providing assurance of test accuracy and reliability applies equally in all these areas. However, as noted above, FDA would continue to exercise its enforcement discretion with respect to testing for drugs of abuse in the law enforcement setting because there are other protections to ensure sample integrity and test accuracy that are not available in the home, workplace, insurance, and sports settings.

FDA believes it is important to give the marketplace time to adjust to any changes in regulatory approach. Therefore, the agency is proposing that the final rule become effective 1 year after publication in the **Federal Register**, but not earlier than 2 years from the date of publication of this proposed rule. FDA believes this provides manufacturers and distributors adequate notice so that, if they wish to market a test sample collection system that uses a specimen for which there is currently no cleared laboratory test (e.g., hair), there is adequate time to conduct the necessary testing and submit the results to FDA for review. Following the 2-year period, a manufacturer or distributor would not be able to market an OTC test sample collection system for drugs of abuse testing unless the underlying test has been cleared by FDA.

Following publication of this proposed rule, FDA will hold a public hearing to solicit additional public comment on its proposal. A separate **Federal Register** notice will announce the date, location, and proposed agenda for the hearing.

FDA's interim policy for drugs of abuse home test sample collection systems will remain in place until the final rule becomes effective. During that time, FDA intends to exercise its enforcement discretion with respect to drugs of abuse test sample collection systems used in the workplace, insurance, or sports settings. Because the exercise of that discretion has been FDA's policy for test sample collection systems used in those settings, the agency believes it is appropriate to provide notice and an opportunity for comment before instituting a change in this policy.

This 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 the 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.

III. Proposed Reclassification

As part of this new regulatory scheme, and in accordance with section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)), FDA, on its own initiative, is proposing to reclassify test sample collection systems for drugs of abuse testing from class III to class I. The device would be identified in proposed § 864.3260 as 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); to 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 to provide access to test results and counseling.

FDA is also proposing that the device be exempt from the premarket notification requirements and, unless it is labeled or otherwise represented as sterile, that it would be exempt from the current good manufacturing practice regulations, with the exception of 21 CFR 820.198, with respect to complaint files. FDA solicits comments on whether there may be other unique circumstances for which the exemption from CGMP regulations would not be appropriate.

Reclassification of a postamendments class III device is governed by section 513(f)(2) of the act. This section provides that FDA may, on its own initiative or in response to a petition, reclassify a postamendments device classified by statute into class III. When FDA reclassifies a postamendments device on its own initiative, the agency follows the same statutory provisions and regulations that apply to reclassifications of such devices in response to a petition.

Under section 513(f)(2) of the act, the agency is authorized, in accordance with section 513(d)(2)(A), to exempt a generic type of device from, among other things, the requirement of premarket notification in section 510(k) of the act (21 U.S.C. 360(k)) after stating the reasons for making such requirement inapplicable. Such an exemption permits manufacturers to introduce into commercial distribution generic types of devices without first submitting a premarket notification to FDA.

The primary risk to health presented by these products is the possibility that they may result in an incorrect diagnosis. No in vitro diagnostic test yields perfect results. Sometimes the test misses the presence of what it is supposed to be detecting (false negative). Sometimes it registers the presence of the substance even though it is not present (false positive). False positives and/or false negatives may also result from an error in the laboratory testing process. Knowing the probability of false negatives and false positives, not just in abstract terms, but why they occur and whether and how the rate varies among different populations, and at various intervals following drug exposure, is essential in order to properly interpret and communicate the results.

FDA believes that this risk to health would be adequately controlled by the proposed restrictions on the sale, distribution and use of these products. The proposed restrictions, which focus on the accuracy and reliability of the underlying test(s), the capability of the laboratory performing the underlying test(s), and the adequacy of the products' labeling, would be sufficient to ensure that drugs of abuse test sample collection systems are accurate and reliable for use in a nonprofessional setting. Further, FDA believes that premarket notification is unnecessary because a manufacturer or distributor can determine for themselves if their product meets the restrictions being proposed in accordance with section 520(e) of the act.

In developing its proposed regulatory approach for these products, FDA relied upon the existence of more than 200 FDA-cleared urine tests for detecting drugs of abuse and several hundred laboratories with sufficient capability to conduct the testing, as well as the agency's experience with premarket review of such test sample collection systems. This information led FDA to conclude that the agency can ensure the accuracy and reliability of OTC drugs of abuse test sample collection systems, while minimizing the disruption to the marketplace, by reclassifying them into class I and exempting them from premarket notification subject to restrictions on the sale, distribution, and use under section 520(e) of the act.

IV. Comments

Interested persons may, on or before July 6, 1998, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday:

1. ''Parents' Access to Tests for Drugs of Abuse;'' Interim Policy; October 3, 1996.

2. Testimony of William Schultz before the House Subcommittee on Oversight and Investigations; February 6, 1997.

3. Summary of Safety and Effectiveness for P950040; Dr. Brown's Home Drug Testing System.

4. Mandatory Guidelines for Federal Workplace Testing; Substance Abuse and Mental Health Services Administration; June 9, 1994.

5. Clinical Laboratory Improvement Amendments of 1988.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this 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.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). The proposed rule has been determined to be a significant regulatory action as defined by the Executive Order and so is subject to review under the Executive Order. 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The proposed 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 would provide benefits to families similar to that which workplace drug testing now provides to employers. First, testing may serve as a deterrent to drug use. Because these products are marketed to parents for testing their children, they have the potential to prevent the initial experimentation with drugs of abuse by children. Next, where test results already indicate the use of drugs, intervention and treatment based on evidence may be initiated earlier than intervention and treatment based on suspicion of drug use alone. 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.

FDA cannot quantify the beneficial effect on the nation's 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 $66 billion in 1990, 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 is a class III medical device requiring a 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 exempt, 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. Because this proposed rule would not require premarket review of the vast majority of OTC test sample collection systems for drugs of abuse testing, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VIII. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements which are subject to review by OMB under the Paperwork Reduction Act of 1995. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

Description: The proposed rule would amend 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 assure 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.

TABLE 1.—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.

FDA requests comments on the accuracy of these estimates concerning the number of entities likely to be affected by the rule and the costs to meet these requirements.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted the collections of information contained in the proposed rule to OMB for review. Other organizations and individuals desiring to submit comments regarding the burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB (address above). Written comments on the information collection requirements should be submitted by April 6, 1998.

List of Subjects

21 CFR Part 809

Labeling, Medical devices.

21 CFR Part 864

Blood, Medical devices, Packaging and containers, Specimen collection systems.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 809 and 864 be 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, 357, 360b, 360c, 360d, 360h, 360i, 360j, 371, 372, 374, 381.

2. Section 809.10 is amended by adding new 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 and are not to be identified in the specimen, a quantitative description of the performance characteristics for those drugs (e.g., sensitivity and specificity), 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. New § 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) 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 FDA 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 *Specimen transport and storage container* is amended in paragraph (a) by adding the following sentence to the end of the paragraph:

§ 864.3250 Specimen transport and storage container.

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

* * * * *

6. New § 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 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, with respect to complaint files.

Dated: September 25, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 98–5521 Filed 3–3–98; 8:45 am]

BILLING CODE 4160–01–F

NATIONAL INDIAN GAMING COMMISSION

25 CFR Chapter III

Minimum Internal Control Standards for Gaming Operations for Indian Lands

AGENCY: National Indian Gaming Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: This document announces the initiation of the rulemaking process and requests information relevant to implementing regulations governing minimum internal control standards for gaming operations operated on Indian lands. The Commission has determined that minimum internal control standards are needed to ensure the integrity of gaming on Indian lands and to safeguard this source of tribal revenues.

DATES: Comments in response to this advance notice must be submitted by April 5, 1998. The Commission will be holding a hearing on this matter on April 1, 1998, in Portland, Oregon.

ADDRESSES: Commentors may submit their comment by mail, facsimile, or delivery to: Minimum Internal Control Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street N.W., Washington, DC 20005. Fax number: 202–632–7066 (not a toll-free number). Public comments may be delivered or inspected from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday.

The public hearing will be held at the Doubletree Hotel at Lloyd Center, Portland, Oregon.

FOR FURTHER INFORMATION CONTACT: Mia Dinh at 202–632–7003, or by facsimile at 202–632–7066 (not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

1. Introduction

The Indian Gaming Regulatory Act (IGRA, or the Act), 25 U.S.C. 2701 *et seq.*, was signed into law on October 17, 1988. The Act established the National Indian Gaming Commission (the Commission). The IGRA was enacted for several purposes, primary among them was to provide a statutory basis for the operation of gaming by Indian tribes as a means of promoting economic development self-sufficiency and strong tribal governments, as well as to provide for the regulation of gaming by Indian tribes adequate to shield them from organized crime. The Commission has determined that minimum internal control standards are needed to ensure the intergrity of gaming on Indian lands and to safeguard this source of tribal revenues.

The IGRA expressly authorizes the Commission to ''promulgate such regulations and guidelines as it deems appropriate to implement the provision of this [Act].'' 25 U.S.C. 2706(b)(10).

2. Advance Notice of Proposed Rulemaking

After consideration of this issue, the NIGC has determined that the appropriate course of action is to publish an Advance Notice of Proposed Rulemaking to collect further information.

Before the NIGC proceeds in this area, it intends to have the benefit of a full airing of the issues through the public comment process.

3. Request for Comments

Public comment is requested to assist the NIGC in the drafting of minimum internal control regulations. Comment is requested on the following issues:

(a) Should standards be tiered based on the physical size of the operation, the amount of the gross revenues derived from gaming, or some other criteria? Please explain.

(b) If yes, what tiers should be adopted. Please explain.

(c) What standards should apply to all operations and what standards should apply to only one or two tiers and not the others?

(d) What are the major internal control issues/problems that Indian gaming operations face?

(e) How long should the Commission allow the tribes to implement internal controls that would comply with the regulations?

The Commission solicits any additional suggestions and/or interpretations regarding the issues raised in this Advance Notice of Proposed Rulemaking.

4. Public Participation

Interested parties are invited to submit comments on any or all of these and other pertinent issues related to minimum internal control regulations by April 5, 1998, in triplicate to Minimum Internal Control Rule Comments, National Indian Gaming Commission, Suite 9100, 1441 L Street N.W., Washington, DC 20005. Fax number: 202–632–7066 (not a toll-free number). All written comments submitted in response to this notice will be available for inspection and copying in the NIGC office from 9 a.m. until noon and from 2 p.m. to 5 p.m. Monday through Friday. All timely written submissions will be considered in determining the nature of any proposal.

Authority and Signature

This Advance Notice of Proposed Rulemaking was prepared under the direction of Larry Rosenthal, Chief of Staff, National Indian Gaming Commission, 1441 L St. N.W., Suite 9100, Washington, DC 20005.

Signed at Washington, D.C. this 27th day of February, 1998.

Larry Rosenthal,

Chief of Staff, National Indian Gaming Commission.

[FR Doc. 98–5656 Filed 3–4–98; 8:45 am]

BILLING CODE 7565–01–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–209276–87]

RIN 1545–AV32

Abatement of Interest; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to notice of proposed rulemaking.

SUMMARY: This document contains a correction to REG–209276–87, which was published in the **Federal Register** on Thursday, January 8, 1998 (63 FR 1086), relating to the abatement of interest attributable to unreasonable errors or delays by an officer or employee of the IRS.

FOR FURTHER INFORMATION CONTACT: David Auclair, (202) 622–4910 (not a toll-free number).