Under the provisions of the law, States may receive allotments only after an application is approved by the Secretary, DHHS. The uniform application format provides States with the forms and instructions for their applications so they can comply with the requirements of the law and regulations implementing the law. The annual burden estimate is shown below:

No. of respondents	No. of responses per respondent	Avg. burden per response	Total annual burden
60	1	561.5 hours.	33,690 hours.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Virginia Huth, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10236, Washington, DC 20503.

Dated: May 31, 1996.

Patricia S. Bransford,

Acting Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 96–14573 Filed 6–7–96; 8:45 am]

BILLING CODE 4162–20–P

Food and Drug Administration

Import and Private Laboratory Communities: Public Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings.

SUMMARY: The Food and Drug Administration's (FDA's) Office of Regulatory Affairs (ORA) is announcing a series of Grassroots Meetings to be held with the import and private laboratory communities. These meetings will follow a prescribed format similar to what was used recently in the Grassroots Regulatory Partnership Meetings held as part of the National Performance Review and will be conducted by key agency officials including ORA's Division of Field Science, the Division of Import Operations and Policy, and other representatives from the field and headquarters.

The purpose of the meetings is to establish a dialogue with the import, domestic, and private laboratory communities, trade associations, and other interested persons. The intent of the dialogue is to explore ways the agency might improve current policy and procedures related to the use of private laboratories to establish product compliance with FDA regulations. After the meetings a report will be prepared outlining a strategy for making positive changes in policy and/or procedures related to the agency's use of analytical data from private laboratories.

DATES: The public meetings are scheduled as follows:

1. Tuesday, June 25, 1996, 9 a.m. to 4:30 p.m., Brooklyn, NY.
2. Friday, June 28, 1996, 9 a.m. to 4:30 p.m., Orlando, FL.
3. Tuesday, July 9, 1996, 9 a.m. to 4:30 p.m., Houston, TX.
4. Thursday, July 11, 1996, 9 a.m. to 4:30 p.m., Oakland, CA.

ADDRESSES: The public meetings will be held at the following locations:

1. Brooklyn—Fort Hamilton Community Club, 101st St. and Fort Hamilton Pkwy., Bldg. 207, Brooklyn, NY.
2. Orlando—Sheraton Plaza Hotel, 1500 Sand Lake Rd., Orlando, FL.
3. Houston—Houston Plaza Hilton, 6633 Travis St., Houston, TX.
4. Oakland—Oakland Federal Bldg., Edward Royball Auditorium, 1301 Clay St., Oakland, CA.

FOR FURTHER INFORMATION CONTACT:

Regarding attendance at the Brooklyn, NY public meeting: George Walden, Small Business Representative Northeast Region, 850 Third Ave., Brooklyn, NY 11232, 718–965–5300, ext. 5528 or FAX 718–965–5759.

Regarding attendance at the Orlando, FL public meeting: Barbara Ward-Groves, Small Business Representative Southeast Region, 60 Eighth St. NE., Atlanta, GA 30309, 404–347–4001, ext. 5256 or FAX 404–347–4349.

Regarding attendance at the Houston, TX public meeting: Marie T. Falcone, Small Business Representative Southwest Region, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247–4982, 214–655–8100, ext. 128 or FAX 214–655–8130.

Regarding attendance at the Oakland, CA public meeting: Mark S. Roh, Small Business Representative Pacific Region, Oakland Federal Bldg., 1301 Clay St., suite 1180–N, Oakland, CA 94612–5217, 510–637–3980 or FAX 510–637–3977.

In addition to this public notice of the meetings, invitations will be sent directly to interested persons representing private laboratories, importers, brokers, independent samplers, scientific and trade associations, accreditation bodies, and domestic users of private laboratories.

Interested persons who have not received an invitation to attend one of these meetings by June 7, 1996, may contact the Small Business Representatives specified above for registration forms.

Persons who are unable to attend, or who cannot be accommodated due to space limitations are invited to provide written comments. Written comments may be submitted to Liza Lehman, Division of Field Science (HFC–140), 5600 Fishers Lane, rm. 12–41, Rockville, MD 20857. Issues submitted in writing will be included for discussion at the meetings and will appear in the final report.

Questions related to these meetings should be directed to Richard A. Baldwin or Liza Lehman (address above) or by calling 301–443–7103 between 8 a.m. and 4:30 p.m.

SUPPLEMENTARY INFORMATION: The following background information is provided for meeting participants. The term ''private laboratory'' refers to those private sector laboratories that conduct analysis on freely marketed, FDA regulated products whose analytical data is submitted to the agency in order to demonstrate a product's compliance with laws and regulations administered by FDA.

Meeting Objectives

(1) To establish a dialogue with the import, domestic, and private laboratory communities; trade associations; and other interested persons on ways the agency might improve current policy and procedures related to the use of private laboratories to establish product compliance with FDA laws and regulations.

(2) To obtain information and views from interested persons on ways the agency might enhance its use of private laboratories to facilitate getting products that comply with applicable laws and regulations to the consumer while removing non-compliant products from the marketplace.

The following workshops will be offered at each meeting:

Workshop I

Workshop I will focus on the following issues:

(1) What practices, procedures, or policies should be changed so that private sector testing expedites the removal of products that do not comply with FDA laws and regulations and the distribution of products that are fully compliant?

(2) What is FDA's experience with how the current process works?

(3) What needs to be changed about the current process?

(4) Why and how?

(5) To what extent are training and education involved?

(6) What are the training needs of private laboratories?

(7) How can FDA, industry, and private laboratories work together to meet these training needs?

Background for Workshop I

FDA has long recognized the role of private laboratories in evaluating the quality and safety of FDA regulated commodities produced both domestically and abroad. Certificates of analysis (or analytical data) issued (or generated) by private laboratories are sometimes used by FDA to assist it in making regulatory decisions. This most often occurs when Certificates of Analysis are received for products offered for import to this country that have been detained without FDA examination due to previous violations or when FDA is concerned about a potential public health problem. FDA may also make compliance decisions with the help of private laboratory results for domestic products that have undergone reconditioning under the terms of a consent decree of condemnation, or to comply with the terms of a consent decree of permanent injunction, so that the firm may lawfully resume operations.

FDA needs to ensure that private laboratories submitting analytical results are capable of performing the analyses and that the results submitted were obtained using reliable and appropriate methods. The current guidance for the review of private laboratory results submitted in support of regulated products is outlined in chapter 21 of the Laboratory Procedures Manual (LPM). The stated purpose of this guidance is to establish a uniform, systematic, and effective approach to ensure that private laboratories conducting analyses on FDA regulated products submit appropriate and reliable data to the agency. Based on LPM chapter 21, the existing mechanism for FDA's acceptance of private laboratory data involves the review of analytical data for scientific validity along with the evaluation of a laboratory's capabilities through assessment visits and audit sampling.

In recent meetings with the private laboratory community, an issue has been raised concerning the lack of uniformity among the FDA District Offices (the Districts) in evaluating private laboratory submissions. FDA is committed to attaining a uniform application of policy and program guidelines among all Districts in the handling of private laboratory submissions. Possible solutions FDA may consider implementing to improve uniformity include: (1) The establishment of a national data base on private laboratories to be used as a mechanism for sharing information among the Districts (see Attachment); (2) providing better coordination of assessment and review efforts through training and strengthening the guidance provided to the Districts; and (3) identifying other ways to foster communications among interested parties involved in private laboratory issues.

Another topic of discussion concerned the training needs of private laboratories. FDA is often asked to answer questions related to sample collection, analytical methodology, and the documentation needed to demonstrate product compliance with FDA laws and regulations. As a result of these inquiries, training seminars have been conducted for private laboratories (and importers) on a variety of topics. Some of these seminars have included training on the use of sample collection and analysis techniques employed by FDA.

FDA would like to better identify the training needs of private laboratories. We would also like to explore mechanisms for effectively providing any necessary training to private laboratories.

Workshop II

Workshop II will focus on the following issues:

(1) How should FDA ensure the competency and proficiency of private laboratories?

(2) What should be FDA's guiding principles in ensuring the competency and proficiency of private laboratories?

(3) What criteria should FDA use to assess integrity and quality of private sector sampling and analysis data?

(4) Under what circumstances should FDA base public health protection decisions on private sector sampling and analysis of regulated products?

(5) What are the barriers or hurdles to what FDA proposes?

(6) How do private laboratories demonstrate their competency to their customers?

(7) Is this mechanism appropriate for FDA to use?

Background for Workshop II

There are several mechanisms the agency could use to ensure the proficiency and integrity of private sector sampling and analysis of regulated products. They include options such as maintaining the current program, adjusting the current program to focus on assuring a more consistent agency approach, adding components to the current program such as an independent sampling and direct reporting requirement, seeking regulatory authority to inspect and impose Good Laboratory Practices regulations on private laboratories, and formally accrediting or recognizing third party accreditations of private laboratories.

FDA currently has serious concerns about the effectiveness of our current program. We presently are unable to ensure the integrity of the sample collection process because we do not require that all samples be collected independently or by qualified sample collection agents. When the sample is collected improperly, or is not truly representative of the lot to be tested, then even the most reliable and effective analytical testing procedures will be invalid. An additional concern regarding our current procedures is that the analytical results obtained by a private laboratory are not required to be submitted directly to the agency for review. Because FDA does not require that an initial or subsequent violative result be submitted directly from the private laboratory, a violative product can be retested until results are obtained that will remove the appearance of a violation. The validity of this laboratory result is, of course, questionable based on previous results, but FDA does not have the information concerning earlier testing on which to base the appropriate consumer protection decision. FDA is considering incorporating these two concepts of mandatory independent sampling, and direct reporting of analytical results by private laboratories to FDA into our current program.

Workshop III

Workshop III will focus on the following issues:

(1) How can FDA best enhance its use of private laboratories to test regulated products?

(2) What is meeting participants' comfort level with shared consumer protection authority and liability?

(3) What are FDA and private sector common interests and how can we capitalize on them?

(4) What are our mutual responsibilities and to whom?

(5) On what basis can FDA and the private sector collaborate?

Background for Workshop

FDA would like to enhance its use of the private sector in monitoring imported foods and possibly other regulated products as well. Several initiatives along this line have already been implemented. For example, the

New York District recently completed a pilot program in which importers of seafood products were allowed to choose between having their products sampled and tested by FDA or by a private laboratory at their own expense. A similar pilot program was conducted in Boston District. The New York and Boston pilot programs are currently being evaluated to see if further pilot studies can be developed to make better use of non-FDA laboratories for monitoring imported products.

Our intention is to improve our current policy and program regarding the use of data from private laboratories. The existing mechanism for the assessment of private laboratories and review of analytical packages may be adequate for our current needs as we move to enhance our use of the private sector for analytical testing, however, we will likely find the need for a more streamlined and effective approach to assessing the competency of a private laboratory and the validity of its test results.

Enhancing FDA's use of private laboratories may also be dependent on the private sector's ability to comply with international standards. As a result, another potential issue for discussion includes the standards for analytical laboratories being developed by the joint Food and Agriculture Organization of the United Nations and World Health Organization's Codex Alimentarius Commission. At the 20th Session of the Codex Committee on Methods of Analysis and Sampling (the Committee), the Committee agreed that certain criteria for quality assurance be adopted by laboratories involved in the official import and export control of foods. The Committee recommendations include compliance with the general criteria for testing laboratories laid down in ISO/IEC Guide 25:1990, ''General Requirements for the Competence of Calibration and Testing Laboratories,'' participation in appropriate proficiency testing schemes, the use validated analytical methods, and the application of internal quality control procedures. These criteria have been referred to the Codex Committee on Food Import and Export Inspection and Certification Systems for consideration and review to be used for the development of objective criteria for assessing the competency of laboratories involved in the testing of foods at the international level. FDA is committed to using international standards whenever appropriate, and to working with international standards organizations like Codex to develop and adopt international standards that provide adequate health protection.

Because of the agency's commitment to international harmonization efforts, the fact that the Committee has made these recommendations is significant to FDA. Successful application of these criteria may be viewed as providing a sound basis for judging the level of quality of both public and private laboratories. Discussion of how (and if) FDA should implement these criteria in evaluating the competency of private laboratories may be included during this workshop.

Attachment—Proposal for the Development of a National Data base on Private Laboratories

An internal FDA-wide private laboratory inventory will be established. This data base is envisioned as being a repository of basic information on private laboratories that routinely submit analytical packages to the agency. The data base will be simple in design serving mainly to foster communication between the Districts.

The following guidance will be issued related to the use of the private laboratory inventory (PLI):

This data base contains information on certain private laboratories that submit analytical results for review to the agency. Private laboratories that do not routinely submit analytical packages to the agency do not appear on this list, since creating a directory of all private laboratories capable of analyzing regulated products, including those laboratories that are associated with regulated industry, or laboratories that have not submitted analytical data for agency review, is not our intention.

The information provided in the PLI is to be used only as a tool to help District personnel make appropriate individual product compliance decisions. The information is not intended to be used as a final evaluation of the acceptability of results for the noted types of analyses from a given private laboratory. As always, Districts should make individual product compliance decisions based on all information available regarding whether or not private laboratory analyses are sufficient to demonstrate product compliance.

This data base may not be treated as an all inclusive listing of private laboratories that are capable of submitting high quality data or analytical results on regulated products to the agency.

The following information will be included in the data base:

Private Laboratory Data
Private Laboratory Name
Private Laboratory Contact/Phone
Complete Mailing Address
Home District Contact/Phone

Submission Data
Type(s) of analytical packages submitted (Chemistry, Micro, Filth, etc)
Date and type of analytical package submission (Date, product, analysis type)
Analysis results
Audit sample results
Narrative describing the audit sample results
Analytical package review (*A*ccepted, accepted with *C*omment, *U*nacceptable)
Analytical package review comments

Private Laboratory Assessment Data
Status of initial assessment records on file per analysis type (complete, in process)
Date of most recent on-site assessment visit per analysis type (month/year)
Narrative results of assessment visit(s) per analysis type.

Dated: May 30, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–14586 Filed 6–7–96; 8:45 am]

BILLING CODE 4160–01–F

Health Care Financing Administration

[MB–098–CN]

RIN 0938–AH30

Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1996; Correction

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Correction notice.

SUMMARY: In the May 9, 1996 issue of the Federal Register (61 FR 21195), we announced the preliminary Federal fiscal year (FFY) 1996 national target and individual State allotments for Medicaid payment adjustments made to hospitals that serve a disproportionate number of Medicaid recipients and low-income patients with special needs. In that notice, we inadvertently omitted the chart that contained the listing of the individual State allotments and the regulation identification number (RIN) in the heading of the notice. In addition, only a portion of the Catalog of Federal Domestic Assistance identification at the end of the document prior to the signatures was included. For the benefit of the readers, we are reprinting the entire notice. The corrected notice reads as follows:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[MB–098–N]

RIN 0938–AH30

Medicaid Program; Limitations on Aggregate Payments to Disproportionate Share Hospitals: Federal Fiscal Year 1996

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice.

SUMMARY: This notice announces the preliminary Federal fiscal year (FFY) 1996 national target and individual