Forth Worth, Texas 76193–0112; telephone (817) 624–5121.

SUPPLEMENTARY INFORMATION:

Background

Heli-Dyne Systems Inc., Hurst, Texas, submitted an application on April 10, 1992, for a Supplemental Type Certificate for installation of an Electronic Flight Instrument System and Flight Management System in a Bell Helicopter Textron, Inc. (BHTI) 230 helicopter. The Model 230 is a 10-passenger, two-engine, 8,400-pound transport category helicopter.

Type Certification Basis

The certification basis established for the BHTI Model 230 includes: Federal Aviation Regulation (FAR) § 21.29 and part 29 effective February 1, 1965, Amendments 29–1 through 29–9; § 29.997, Amendment 29–10; § 29.1401, Amendment 29–11; §§ 29.25(c), 29.801, 29.865, 29.1555(c), 29.1557(c), Amendment 29–12; § 29.927(b)(2), Amendment 29–17; Instrument Flight Rules (IFR) requirements dated December 15, 1978; FAA Exemption No. 2789, § 29.811(f)(1); FAA Exemption No. 4395, § 29.855(a); selected sections of Part 29 up to and including Amendment 29–26 as follows: §§ 29.1, 29.21 thru 29.175, 29.231 thru 29.235, 29.251 thru 29.361, 29.411, 29.471 thru 29.493, 29.501, 29.547 thru 29.549, 29.561 thru 29.603, 29.607 thru 29.609, 29.611 thru 29.629, 29.683, 29.723 thru 29.727, 29.731, 29.735, 29.771 thru 29.775, 29.785, 29.831, 29.855, 29.861 thru 29.863, 29.873 thru 29.917, 29.931, 29.939 thru 29,953, 29.955, 29.961, 29.993 thru 29.997, 29.1011 thru 29.1023, 29.1027 thru 29.1105, 29.1121 thru 29.1123, 29.1141, 29.1143 thru 29.1145, 29.1163 thru 29.1307, 29.1321 thru 29.1322, 29.1327, 29.1331 thru 29.1333, 29.1337, 29.1359 thru 29.1381, 29.1401, 29.1431, 29.1461 thru 29.1505, 29.1517 thru 29.1521, 29.1527, 29.1541 thru 29.1543, 29.1549 thru 29.1551, 29.1555 thru 29.1559, 29.1581 thru 29.1587, Appendix B; the noise standards of part 36 and ICAO Annex 16; and Canadian Airworthiness Manual 529; 529.1301–1, 529.1557(c)(3), 529.581, 529.1093(b)(1)(ii).

If the Administrator finds that the applicable airworthiness regulations do not contain adequate or appropriate safety standards for the Model 230 helicopter because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.101(b)(2) to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with § 11.49 of the FAR, after public notice, as required by §§ 11.28 and 11.29(b), and become a part of the type certification basis in accordance with § 21.101(b)(2). In addition to the applicable airworthiness regulations and special condition, the Model 230 must comply with the noise requirements of part 36.

Novel or Unusual Design Feature

The BHTI Model 230 helicopter, at the time of application, was identified as incorporating electrical, electronic or a combination electrical, electronic systems that will be performing functions critical to the continued safe flight and landing of the helicopter. The electronic flight instrument system performs the attitude display function. The display of attitude, altitude, and airspeed to the pilot is critical to the continued safe flight and landing of the helicopter while operating in accordance with IFR in instrument meteorological conditions.

If it is determined that this helicopter will incorporate other electrical, electronic systems or a combination electrical, electronic systems performing critical functions, those systems also will be required to comply with the requirements of this special condition.

Discussion of Comments

Notice of Proposed Special Condition No. SC–92–4–SW was published in the **Federal Register** on October 15, 1992, (57 FR 47295). No comments were received. Therefore, the special condition is adopted as proposed.

Conclusion

This action affects only one unusual or novel design feature on one series of helicopters. It is not a rule of general applicability and affects only the manufacturer who applied to the FAA for approval of these features on the affected helicopters.

The FAA has determined that good cause exists for making this rule effective in less than 30 day after publication. This special condition affects only a single type design. No comments were received in response to the Notice. Further, the applicant would experience an undue economic penalty due to a delay in the delivery of the affected helicopters if the effectivity of this rule of special effect is delayed. Therefore, this special condition is made effective immediately upon issuance.

List of Subjects in 14 CFR Parts 21 and 29

Aircraft, Air transportation, Aviation safety, Rotorcraft, Safety.

The authority citation for this special condition is as follows:

Authority: 49 U.S.C. 1344, 1348(c), 1352, 1354(a), 1355, 1421 through 1431, 1502, 1651(b)(2); 42 U.S.C. 1857f–10, 4321 et seq.; E.O. 11514; 49 U.S.C. 106(g).

The Special Condition

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special condition is issued as part of the type certification basis for the Bell Helicopter Textron, Inc. Model 230 helicopter:

Protection for Electrical/Electronic Systems From High Intensity Radiated Fields.

Each system that performs critical functions must be designed and installed to ensure that the operation and operational capabilities of these critical functions are not adversely affected when the helicopter is exposed to high intensity radiated fields external to the helicopter.

Issued in Fort Worth, Texas, on July 7, 1993.

James D. Erickson,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 93–17167 Filed 7–19–93; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 291

[Docket No. 93N–0040]

Levo-ALPHA-Acetyl-Methadol (LAAM) in Maintenance; Revision of Conditions for Use in the Treatment of Narcotic Addiction

AGENCIES: Food and Drug Administration and the National Institute on Drug Abuse, HHS.

ACTION: Interim rule; request for public comment.

SUMMARY: The Food and Drug Administration (FDA), in consultation with the National Institute on Drug Abuse (NIDA), is issuing interim rules revising conditions for the treatment of narcotic addiction to provide standards for the use of Levo-*Alpha*-Acetyl-Methadol (LAAM) in the maintenance treatment of narcotic addicts. This action will allow narcotic treatment

programs to provide an additional drug for use in the maintenance treatment of narcotic addicts. FDA is issuing these regulations as an interim rule with a request for public comment.

DATES: Effective July 20, 1993; written comments by September 20, 1993.

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

FOR FURTHER INFORMATION CONTACT: Thomas Kuchenberg, Center for Drug Evaluation and Research (HFD–362), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8046.

SUPPLEMENTARY INFORMATION:

I. Background

Section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91–513) requires the Secretary of Health and Human Services (the Secretary) to determine the appropriate methods of professional practice for the medical treatment of narcotic addiction. In addition, the Narcotic Addict Treatment Act of 1974 (Pub. L. 93–281) amended the Controlled Substances Act (21 U.S.C. 823) to require that practitioners who wish to dispense narcotic drugs to individuals for the maintenance treatment or detoxification treatment of narcotic addiction must be registered annually with the Department of Justice, Drug Enforcement Administration (DEA). Registration depends, in part, upon a determination by the Secretary that the applicant is qualified, under treatment standards established by the Secretary, to provide such treatment. In addition, the applicant must comply with standards established by the Secretary (after consultation with DEA) respecting the quantities of narcotic drugs that may be provided for unsupervised use by individuals in such treatment. Finally, the applicant must comply with standards established by DEA respecting security of stocks of narcotic drugs used for such treatment and maintenance of records on such drugs.

Regulations governing conditions for the use of narcotic drugs in the maintenance and detoxification treatment of narcotic addicts can be found in part 291 (21 CFR part 291). Section 291.505 (commonly referred to as the methadone regulation) is currently applicable to methadone, the only narcotic drug now approved for use in the maintenance and detoxification treatment of narcotic addiction. The methadone regulation delineates the appropriate methods of professional practice for medical treatment of the narcotic addiction of various categories of addicts and provides close controls over the distribution, administration, and dispensing of methadone in treatment programs. Elements of the methadone regulation include general provisions regarding treatment program organizational structure and approval requirements, minimum standards for patient evaluation and admission, minimum medical and rehabilitative support services, and program sanctions.

The methadone regulation has, in general, facilitated the efficient and safe management and rehabilitation of narcotic addicts. The use of methadone has been central to narcotic drug treatment efforts for over two decades and has helped many narcotic addicts decrease the intravenous (IV) use of illegal narcotic drugs and avoid human immunodeficiency virus (HIV) infection, which is known to be transmitted by sharing contaminated hypodermic needles. Although methadone has been widely accepted as the standard narcotic treatment for heroin dependence since its introduction, there have been important changes in the addict population in the last 20 years. These include the periodic introduction and popularity of "new" illegal drugs and the tendency for an increasing number of individuals to simultaneously abuse a number of these substances. These factors have led to a growing need by narcotic treatment professionals for additional treatment options and has stimulated an ongoing search for alternative medications.

II. NIDA'S Medication Development Program

The Anti-Drug Abuse Act of 1988 (Pub. L. 100–690) authorized expanded research to make drugs other than methadone available for treatment of intravenous opiate addiction. This law expanded NIDA's efforts in data collection, treatment evaluation, demonstration projects, and development of new and improved treatment methods, including additional pharmacologic agents to treat drug abuse.

NIDA formed a Drug Development Task Force to solicit support from the pharmaceutical industry, administer grants to investigators, and oversee toxicity tests, clinical trials, and computer-assisted screening of potentially helpful drugs. In fiscal year 1989, NIDA established the Medications Development Program to research and develop new and more effective medications to treat addictive disorders, most notably opiate and cocaine addiction. NIDA also established treatment research units that have a major role in evaluating new medications and conducting the necessary preliminary clinical trials of the drug development process. Promising new drugs are to be guided through final clinical testing and the new drug approval process so as to be marketed for the treatment of drug addiction through agreements reached with the sponsoring pharmaceutical companies. NIDA's role in the development of new drugs is further delineated by the ADAMHA Reorganization Act (Pub. L. 102–321) enacted on July 10, 1992 (ADAMHA means the Alcohol, Drug Abuse, and Mental Health Administration). Section 123 of this legislation gives NIDA's Medications Development Program expanded authority to encourage and promote the development and use of medications to treat drug addiction.

In addition to developing treatment drugs, NIDA plans to use drug abuse research to target drugs that may fulfill certain therapeutic goals. Technological advances and research have led to an expanded understanding of how drugs interact with the brain. Using this understanding, the goal is to develop drug abuse medications that:

(1) Block the effects of abused drugs;

(2) reduce the craving for abused drugs;

(3) moderate or eliminate withdrawal symptoms;

(4) block or reverse the toxic effects of abused drugs; or

(5) prevent relapse in persons who have been detoxified from drugs of abuse. It is therefore important that regulations governing narcotic treatment programs are able to accommodate the potential use of a variety of treatment medications.

NIDA and FDA thus share responsibility for providing a wider range of treatment drugs to programs. NIDA is charged with developing the new medications and FDA with both determining whether such medications are effective and developing standards for their safe use. To encourage cooperation, the ADAMHA Reorganization Act states that the Director of NIDA is to "conduct periodic meetings with the Commissioner of Food and Drugs to discuss measures that may facilitate the approval process of drug abuse treatments."

It is anticipated that the Medications Development Program will expand the number of drug products available for the treatment of drug abuse. Indeed, a number of addiction treatment

medications with potential for clinical use are already in clinical trials. One product to emerge from this process is LAAM, a narcotic drug which has been approved for maintenance treatment of narcotic addiction.

III. Justification for Dispensing with Prior Notice and Opportunity for Public Comment

The Administrative Procedure Act (5 U.S.C. 553) requires agencies to follow certain procedures for informal rulemaking, including publication of proposed rules in the **Federal Register** with an opportunity for public comment. Section 553(b)(B) allows agencies to dispense with prior notice and opportunity for public comment if the agency finds for good cause that use of such procedures is impracticable, unnecessary, or contrary to the public interest.

FDA and NIDA have determined that good cause exists for publication of these rules without prior notice and opportunity for public comment and without a delayed effective date since such procedures are contrary to the public interest and unnecessary. It is in the public interest for LAAM to be available as a maintenance treatment for narcotic addiction simultaneous with its approval rather than for the drug to be unavailable for the period of time it would take the agency to publish proposed and final rules based on the approval. This additional treatment can help to reduce the mortality rate among addicts and the possible spread of HIV and other diseases among addicts and the general population by decreasing IV drug abuse.

Even before the onset of the HIV epidemic, the mortality rates among addicts exceeded that of nonaddicts. A significant factor in this higher mortality is the insanitary conditions which often accompany the administration of illegal drugs. These conditions, particularly the practice of needle sharing, have facilitated the spread of a number of disorders including pneumonia, hepatitis A and B, immunologic abnormalities, and HIV disease. In a January 6, 1993, FDA and Substance Abuse and Mental Health Administration (SAMHSA) regulation providing for interim maintenance treatment, the Secretary made a finding that "the preponderance of scientific research indicates that IV abuse of drugs is, in fact, a primary pathway for HIV disease transmission and as such constitutes a major public health problem" (58 FR 495 at 496). It is important to note that while the addict population is particularly susceptible, these diseases can also be spread to the nonaddict population. Evidence also indicates that participation in a maintenance treatment program reduces IV drug abuse, the potential for disease transmission, and its associated mortality rate. In the interim maintenance rule published in the **Federal Register** of January 6, 1993, the Secretary also found that "the preponderance of scientific research indicates that the medically supervised dispensing of methadone continues to be an effective method of reducing dependence on heroin and other morphine-like drugs" (58 FR 495 at 496). It is, therefore, important to facilitate actions that enable programs to enhance services and more effectively interdict IV drug abuse.

LAAM will provide treatment programs with an additional option for the treatment of addiction and, because of the longer duration of its effects, will provide programs with more flexibility. The longer duration of LAAM may also help alleviate the overcrowding currently causing problems in some programs. A 1992 FDA survey indicates that a number of the areas experiencing a shortage of treatment capacity are also areas experiencing increases in the incidence of HIV disease among IV drug abusers. Congress addressed the problem of inadequate treatment capacity by including a provision in the 1992 ADAMHA Reorganization Act, which authorizes States to permit interim methadone maintenance in areas with a shortage of treatment slots. Because it is recommended that patients be given LAAM three times a week or every other day, as opposed to the daily dosing generally recommended for methadone, use of LAAM may allow programs to increase the number of comprehensive treatment positions.

While LAAM has been approved for the purpose of treating narcotic addicts, it continues to be the subject of ongoing clinical research. This research and testing may lead to a reevaluation of current recommendations for, or restrictions on, the use of the drug by certain categories of patients. Any changes resulting from such ongoing studies or with experience gained through use of LAAM in treatment programs will be incorporated in a final rule.

In addition to the public interest in having LAAM available for treatment use as soon as possible, prior notice and comment procedures and delayed effective date are unnecessary. The rules reflect FDA's approval of a new drug application (NDA) for LAAM, a process not subject to public participation. In addition, the regulations merely add LAAM as an available treatment drug within the existing structure of the current narcotic addiction treatment regulations which were subject to notice and comment rulemaking. The current regulations, published in the **Federal Register** of March 2, 1989 (54 FR 8954), changed many methadone specific terms to narcotic treatment drug general terms in describing general conditions for use of narcotic drugs to treat narcotic addiction. Thus, the current regulations appear to have anticipated the incorporation of additional approved treatment drugs with conforming changes to provisions such as 21 CFR 291.505(b)(2)(v). These rules make further changes from methadone specific terms to narcotic treatment general terms to reflect the approval of LAAM as a maintenance treatment for narcotic addiction.

IV. LAAM Maintenance Treatment

LAAM was developed in 1948 as a synthetic congener of methadone. Originally tested as a narcotic analgesic in Germany, it attracted attention in this country in the 1970's as a potential treatment drug for heroin addiction. In contrast to methadone, the effects of orally administered LAAM do not start until several hours after administration and last an average of 2 to 3 days. As a result, LAAM produces less of an opiate "high" and narcotic sedation than heroin and other morphine-like drugs. There was an initial attempt to examine its potential as an addiction-treatment drug, and a total of 27 separate studies involving approximately 6,000 opiate-dependent patients were conducted with LAAM between 1969 and the early 1980's. Thereafter, the effort to develop LAAM's narcotic treatment potential languished until passage of the 1988 Anti-Drug Abuse Act gave NIDA the economic and legal resources necessary to renew sponsorship of the drug. Because most of the original research was conducted during the first period of LAAM development in the 1970's, updated studies were conducted to verify the recommended labeling for LAAM and to gain further experience with use of the drug in women and patients who are HIV positive. There was also a need to learn more about the drug's effectiveness in the current addict population, a population that has a higher incidence of hepatitis B and other liver diseases and is more prone to multidrug abuse than the population originally studied in the 1970's.

Because of these and other considerations of safety that had to be addressed before approval of an NDA for LAAM, NIDA sponsored a label assessment study of LAAM for use in

maintenance treatment of narcotic addiction. The results of that study indicated LAAM is effective in the long-term treatment of narcotic addiction.

Although a provision permitting interim maintenance under certain conditions was published on January 6, 1993 (58 FR 495), the last extensive revision of the methadone regulation appeared in the **Federal Register** of March 2, 1989 (54 FR 8954). As discussed in the preamble to the March 2, 1989, final rule, these revisions were designed to streamline the regulation and to promote more efficient operation of narcotic treatment programs. Among these changes were revisions that established as general requirements provisions that had previously applied solely to methadone, e.g., methadone treatment program became narcotic treatment program and methadone maintenance treatment became maintenance treatment. These revisions resulted in a framework of program requirements such as minimum standards for patient evaluation and admission, minimum standards for medical and rehabilitative support services, and program sanctions that can be applied to any new drug authorized for use in the treatment of drug abuse.

FDA and NIDA are now authorizing the use of LAAM in the maintenance treatment of narcotic addicts. LAAM is the first of several new narcotic treatment drugs under development that are to be guided, as previously discussed, through final clinical testing and the new drug approval process according to agreements reached with the sponsoring pharmaceutical companies.

In order to provide for the use of LAAM and other narcotic treatment drugs while retaining the current requirements for the use of methadone in a narcotic treatment program, the regulations are restructured to provide: (1) General requirements applicable to all narcotic treatment programs regardless of the drug used in treatment; (2) specific requirements applicable solely to LAAM; and (3) specific requirements applicable solely to methadone. As additional treatment drugs are approved, provisions that are critical to the safe use of a product in a treatment program will be included in the regulation.

V. Description of the Interim Final Rule

Current § 291.501 was promulgated in 1977 and reflected the then-investigational use of methadone in narcotic addict treatment programs and concerns about possible abuses that might arise from such use. Since 1977, widespread experience with methadone maintenance treatment has demonstrated the ability of these programs to help certain drug abusers lead more productive and independent lives. As a result, current § 291.501(a) speaks of a need for further research on what is now a well-understood drug. This interim final rule deletes these and other references particular to methadone in §§ 291.501 and 291.505 and replaces them with a more general statement recognizing that the use of narcotic drugs in maintenance treatment can be an effective part of the management and rehabilitation of selected addicts.

Current § 291.501(a) reflects the earlier, experimental, nature of maintenance treatment and calls for further research. The interim final rule replaces such language with a statement that interested and qualified parties should be allowed to use approved narcotic drugs in the treatment of addiction. It will also require that such drugs have an approved NDA for such use.

Under current § 291.505(b)(2)(v), methadone is the only drug approved for use in treatment programs. In this interim final rule, § 291.505(b)(2)(v) adds LAAM to the list of drugs available for the treatment of narcotic addiction.

Section 291.505(c) details some of the requirements for obtaining approval to operate a treatment program, including necessary program services and applications. The interim final rule changes the title of Form FDA–2632, "Application for Approval of Use of Methadone in a Treatment Program," to "Application for Approval of Use of Narcotic Drugs in a Treatment Program." Similar title changes to forms occur elsewhere in part 291 in order to reflect the potential availability of a variety of treatment drugs.

The minimum standards for admission to a treatment program are found at § 291.505(d). Before admission, program personnel take a history of addiction from the new patient, and current § 291.505(d)(1)(i)(C) requires that this information be recorded before any methadone is administered to the patient. In order to provide for drugs other than methadone, the interim final rule deletes the reference to methadone and requires that the history of addiction be recorded before administration of any narcotic treatment drug.

Current § 291.505(d)(1)(ii) requires that treatment programs ensure that a patient's participation in a treatment program is voluntary, and that all relevant facts regarding use of the treatment drug are clearly and adequately explained to the patient entering the program. The patient must also sign consent form FDA–2635. If the prospective patient is under the age of 18, this consent form is to be signed by a parent, guardian, or responsible adult designated by the State authority. To provide for narcotic drugs other than methadone, the interim final rule changes the title of FDA–2635 from "Consent to Methadone Treatment" to "Consent to Treatment with an Approved Narcotic Drug."

The current regulation exempts certain categories of patients from the general requirements governing admission to treatment programs. Although a number of patient categories are the subject of specialized labeling under 21 CFR 201.57 (e.g., pregnancy, nursing mothers), the unique nature of narcotic treatment drugs has made it necessary to extend additional regulatory protection to certain categories of patients.

Under the existing regulation, pregnant patients with a history of drug addiction may be placed on methadone maintenance and are to be given an opportunity to obtain prenatal care (§ 291.505(d)(1)(iii)(B)(*1*)).

Because LAAM is not approved for use during pregnancy or while nursing, patients who are or become pregnant cannot be started or continued on LAAM except by written order of a physician who determines this to be the best choice of therapy for the patient. Clinics providing treatment with the drug must advise all patients of childbearing potential of the risks of LAAM and make a medical evaluation available to all patients who become pregnant while taking the drug. In addition, the interim final rule, at § 291.505(d)(1)(iii)(B)(*6*), requires that any female patient of childbearing potential be tested for pregnancy before admission to LAAM maintenance treatment and that pregnancy tests be performed monthly thereafter. Where initial urine screens are positive, the program may wish to employ other tests to confirm the pregnancy. In order to ensure the accuracy of such testing, the interim final rule requires that such tests be performed in a laboratory approved under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (Pub. L. 100–578) or certified by a State or private accrediting body approved by the Health Care Financing Administration. The purpose of CLIA '88 is to ensure that laboratories provide accurate and reliable test results and that individuals are not adversely affected by substandard laboratory operations and testing procedures.

Another group of patients subject to slightly different admission standards are those who have been previously

treated. Existing § 291.505(d)(1)(iii)(C) states that, within certain circumstances, patients who have been previously treated and later voluntarily detoxified from maintenance treatment may be readmitted without evidence of current addiction. For patients readmitted under these standards, the quantity of take-home medication is subject to the clinical judgment of the admitting program physician and can be no greater than what would have been allowed under previous treatment. Because there is currently no adequate assessment of the risks of allowing take-home for LAAM, § 291.505(k)(1)(iii) provides for no take-home privileges for LAAM. Therefore, § 291.505(d)(1)(iii)(C) is revised to limit take-home medication for previously treated patients to those drugs for which take-home privileges are permitted.

Current § 291.505(d)(1)(iv) authorizes maintenance treatment of adolescent patients under specified circumstances. However, because there are no adequate studies to support the use of LAAM in those younger than 18, the interim final rule adds a new provision (§ 291.505(d)(1)(iv)(B)) that prohibits any person under 18 years of age from entering LAAM maintenance treatment.

Current § 291.505(d)(3)(i) requires patients to be medically evaluated on admission to a treatment program. As part of this evaluation, the regulation mandates a number of laboratory examinations. Because FDA has not approved LAAM for use during pregnancy, the interim final rule revises § 291.505(d)(3)(i) to require an initial pregnancy test for women of childbearing potential seeking admission to LAAM maintenance treatment.

Current § 291.505(d)(4) requires that a treatment program provide a comprehensive range of medical and rehabilitative services to its patients and delineates the general responsibilities of the medical director and program physicians and the use of health care professionals in narcotic treatment programs. For improved organization of related requirements, the interim final rule transfers the provisions of current § 291.505(d)(6)(ii), which addresses the responsibilities of authorized dispensers of narcotic drugs, to new § 291.505(d)(4)(v). Accordingly, current § 291.505(d)(6)(ii) is removed and reserved.

Section 291.505(d)(6) delineates the requirements regarding the use and administration of methadone in a treatment program. The interim final rule revises the heading of the paragraph to make it clear that this paragraph applies solely to the use of methadone in a treatment program.

VI. Narcotic Treatment Regulations

As noted, this interim final rule is intended to further the transformation of current § 291.505 into a regulation that establishes standards for narcotic treatment programs to include all drugs approved for treatment of addiction. Accordingly, this interim final rule redesignates § 291.505(k) as § 291.505(l) and adds new § 291.505(k), which addresses the use of approved narcotic drug products other than methadone in a treatment program.

The agencies believe that certain aspects of the administration of LAAM must be codified to protect patients and, to that end, the interim final rule will add certain provisions under new § 291.505(k)(1). These provisions provide specific dosing requirements for LAAM, prohibit take-home use of the drug, and describe circumstances under which a LAAM patient may be temporarily transferred to methadone.

Subsequent paragraphs under new § 291.505(k) will provide specific requirements for future narcotic drugs approved for the treatment of narcotic addiction. This approach will enable the agencies to promulgate, if necessary, additional requirements for narcotic drug products approved in the future. Additional regulatory requirements will be examined during the NDA review process, and factors that would help determine whether specific regulatory requirements would be needed include the drug product's safety profile, the potential for diversion to illicit use, and other factors. This approach recognizes the importance of the approved product labeling, which results from the rigorous NDA review process, and which facilitates the safe and effective use of new narcotic treatment drug products.

New § 291.505(k)(1)(i) requires that patients be administered LAAM no more frequently than every other day at doses, frequencies, and under conditions of usage described in approved labeling. The usual dosing regimen is thrice weekly. For a patient with an unknown tolerance to opioids, the initial dose of LAAM should not exceed 40 milligrams (mg). Caution in administering an initial dose of LAAM is particularly important because the effects of LAAM are not felt until several hours after administration. Provided there is a demonstrated need, this provision does not preclude additional dosing. For a patient previously stabilized on methadone maintenance, the initial dose will be 1.3 times the daily methadone dose and is not to exceed 120 mg. The interim final rule requires a licensed physician to assume responsibility for the amount of the drug dispensed and to record, date, and sign in each patient's record each change in dosage schedule. Any single dose after the initial dose that is greater than 140 mg must be justified in the patient's record by the administering licensed physician. LAAM, under § 291.505(k)(1)(ii), is to be administered in an oral liquid formulation and to be distinguished from methadone by measures such as contrasting color and taste that ensure that the two medications are easily distinguished. In addition, § 291.505(k)(1)(iii) prohibits take-home doses of LAAM. Any LAAM patient who would be eligible for take-home doses of methadone may be switched to methadone when exceptional circumstances make it impossible for the patient to conform to the applicable LAAM dosing schedule.

Former § 291.505(d)(13) mandated that record systems comply with all Federal and State reporting requirements relevant to methadone. This interim final rule revises § 291.505(d)(13) to require compliance with all Federal and State reporting requirements relevant to the treatment of narcotic addiction.

As noted, the interim final rule changes the methadone specific title of most program forms to one applicable to all narcotic treatment drugs. However, since LAAM is not approved for detoxification, new § 291.505(h)(1) retains the methadone-specific title of Form FDA 2636, "Hospital Request for Methadone Detoxification Treatment."

VII. Environmental Impact

The agencies have determined under 21 CFR 25.24(a)(8) and (a)(11) 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.

VIII. Economic Impact

FDA and NIDA have examined the economic consequences of this interim final rule in accordance with Executive Order 12291 and the Regulatory Flexibility Act (Pub. L. 96–354). There are two provisions in this rule that will impose additional costs on those narcotic treatment programs that choose to use LAAM for treating patients:

First, § 291.505(d)(1)(iii)(B)(*6*) requires that an initial pregnancy test and analysis shall be performed for each prospective female patient of childbearing potential before admission to LAAM maintenance treatment, and

that monthly pregnancy tests and analyses shall be performed on these female patients. Information obtained from NIDA indicates that this requirement will result in annual costs totaling approximately $820,000. This estimate is based on approximately 34,000 female patients of childbearing age approximately 25 percent of whom will be candidates for LAAM therapy, and approximately $8 for each test analysis, repeated monthly.

Second, NIDA has estimated that the cost of administering LAAM is approximately $2.85 more per patient per week than the cost of administering methadone. Assuming that one-fourth of the approximately 104,000 patients currently enrolled in narcotic treatment programs is administered LAAM (approximately 26,000 patients), the additional cost for the patients who receive LAAM would be approximately $74,000 per week, or $3.8 million per year.

Therefore, the total cost to narcotic treatment programs resulting from this regulation is approximately $4.6 million per year. Importantly, this is the estimated additional cost associated with administering LAAM compared to existing therapy with methadone. Because LAAM can be administered on an every other day, or thrice weekly schedule, the concomitant reduction in clinic attendance will reduce the overall treatment costs to treatment programs that choose to provide LAAM therapy. This anticipated reduction in overall treatment cost should more than offset the estimated additional costs associated with administering LAAM.

Accordingly, the agencies conclude that this rule is not a major rule as defined by Executive Order 12291. For similar reasons, the agencies certify, in accordance with Pub. L. 96–354, that this rule will not have a significant impact on a substantial number of small entities.

IX. Paperwork Reduction Act

This interim final rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980. However, most of the recordkeeping and reporting requirements that would result from this interim rule have already been approved by OMB through July 31, 1995, under number 0910–0140, "Methadone in Maintenance Detoxification, Joint Revisions of Conditions for Use."

There are two new information collection requirements in this interim rule that were not included in number 0910–0140. There are, as explained below, no measurable burden estimates for these requirements.

1. Section 291.505(k)(1)(i)(C) requires that a licensed physician assume responsibility for the amount of narcotic drug administered or dispensed and shall record, date, and sign or countersign in each patient's record each change in dosage schedule. This provision, which applies to LAAM, contains the same requirements as current § 291.505(d)(6)(ii), which pertains to methadone. These requirements are customary and usual practices within the medical and rehabilitative communities, and require no assessment for respondent burden hours or costs.

2. Section 291.505(l) requires that the sponsor indicate on forms FDA–2632, FDA–2633, FDA–2635, or FDA–2636 which treatment drug is being utilized. These forms are approved by OMB under number 0910–0140. The burden associated with this requirement is negligible.

X. Request for Comments

Interested persons may, on or before September 20, 1993, submit to the Dockets Management Branch (address above) written comments regarding this interim final rule. 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.

List of Subjects in 21 CFR Part 291

Health professions, LAAM, Methadone, Reporting and recordkeeping requirements.

Therefore, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, the Narcotic Addict Treatment Act of 1974, and applicable delegations of authority thereunder, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 291 is amended as follows:

PART 291—DRUGS USED FOR TREATMENT OF NARCOTIC ADDICTS

1. The authority citation for 21 CFR part 291 continues to read as follows:

Authority: Secs. 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 371); 21 U.S.C. 823; secs. 301(d), 548, 1976 of the Public Health Service Act (42 U.S.C. 241(d), 290ee–3, 300y–11); 42 U.S.C. 257a.

2. Section 291.501 is revised to read as follows:

§ 291.501 Narcotic drugs in the maintenance treatment of narcotic addicts.

(a) The Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, recognize that the use of narcotic drugs in the prolonged maintenance of narcotic dependence has been shown to be an effective part of a total treatment effort in the management and rehabilitation of selected narcotic addicts. It is also recognized that a number of dangers and possible abuses may arise from such efforts if professional services and controls are inadequately applied.

(b) Therefore, the Commissioner of Food and Drugs, the Director of the National Institute on Drug Abuse, and the Administrator of the Drug Enforcement Administration, Department of Justice, agree that interested professionals, municipalities, and organizations should be allowed to use narcotic drugs in the medical treatment of narcotic addiction within a framework of adequate controls designed to protect the individual patients and the community. Narcotic drugs that are to be used as part of the treatment of narcotic addiction must have an approved new drug application for such use. To facilitate this purpose, the Food and Drug Administration, the National Institute on Drug Abuse, and the Drug Enforcement Administration, Department of Justice, have jointly agreed upon acceptable conditions for the use of narcotic drugs in a treatment program, which are set forth in § 291.505. In addition, such other provisions of the Federal narcotic laws and regulations as are applicable must also be observed.

3. Section 291.505 is amended by revising paragraphs (b)(2)(v), (b)(2)(vi)(D), (c)(4)(i), (c)(4)(ii), the last sentence in paragraph (d)(1)(i)(C), paragraph (d)(1)(ii), the first sentence in paragraph (d)(1)(iii)(B)(*1*) and by removing the word "methadone" in the two places it appears in paragraph (d)(1)(iii)(B)(*1*), by adding new paragraph (d)(1)(iii)(B)(*6*), by revising the second sentence in paragraph (d)(1)(iii)(C), paragraph (d)(1)(iv), by adding a new sentence after the second sentence in paragraph (d)(3)(i), by adding new paragraph (d)(4)(v), by revising the paragraph headings of paragraphs (d)(6) and (d)(6)(i), by removing paragraph (d)(6)(ii) and reserving it, by revising the second sentence in paragraph (d)(13)(i), in paragraph (f)(2)(viii) by removing the phrase "paragraph (k) of this section" and adding in its place "paragraph (l) of this section", by revising paragraph

(h)(1), by redesignating paragraph (k) as paragraph (l) and revising it, and by adding new paragraph (k) to read as follows:

§ 291.505 Conditions for the use of narcotic drugs; appropriate methods of professional practice for medical treatment of the narcotic addiction of various classes of narcotic addicts under section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970.

* * * * *

(b) * * *

(2) * * *

(v) *Approved narcotic drugs for use in treatment programs.* The following narcotic drugs have been approved for use in the treatment of narcotic addiction: Methadone and Levo-*Alpha*-Acetyl-Methadol (LAAM).

(vi) * * *

(D) Requests for authorization should be submitted to the address specified in paragraph (l) of this section.

* * * * *

(c) * * *

(4) * * *

(i) Form FDA–2632 "Application for Approval of Use of Narcotic Drugs in a Treatment Program." This form, required by paragraph (l) of this section, shall be completed and signed by the program sponsor and submitted in duplicate to the Food and Drug Administration and the State authority.

(ii) Form FDA–2633 "Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program." This form, required by paragraph (l) of this section, shall be completed and signed by each licensed physician authorized to administer or dispense narcotic drugs and submitted in duplicate to the Food and Drug Administration and the State authority. The names of any other persons licensed by law to administer or dispense narcotic drugs working in the program shall be listed even if they are not responsible for administering or dispensing the drug at the time the application is submitted.

* * * * *

(d)(1) * * * (i) * * *

(C) * * * The program physician shall complete and record the statement before the program administers any narcotic drug to the patient.

(ii) *Voluntary participation, informed consent.* The person responsible for the program shall ensure that: A patient voluntarily chooses to participate in a program; all relevant facts concerning the use of the narcotic drug used by the program are clearly and adequately explained to the patient; all patients, with full knowledge and understanding of its contents, sign the "Consent to Treatment with an Approved Narcotic Drug" Form FDA–2635 (see paragraph (l) of this section); a parent, legal guardian, or responsible adult designated by the State authority (e.g., "emancipated minor" laws) sign for patients under the age of 18 the second part of Form FDA–2635 "Consent to Treatment with an Approved Narcotic Drug."

(iii) * * *

(B) *Pregnant patients.* (*1*) Pregnant patients, regardless of age, who have had a documented narcotic dependency in the past and who may return to narcotic dependency, with all its attendant dangers during pregnancy, may be placed on a comprehensive maintenance regimen, except as provided in paragraph (d)(1)(iii)(B)(*6*) of this section. * * *

* * * * *

(*6*) Patients who are or become pregnant shall not be started or continued on LAAM, except by the written order of a physician who determines this to be the best choice of therapy for that patient. Clinics providing treatment with LAAM must advise all patients of childbearing potential of the risks of LAAM and make a medical evaluation available to all patients who become pregnant while taking the drug. An initial pregnancy test shall be performed for each prospective female patient of childbearing potential before admission to LAAM comprehensive maintenance treatment and monthly pregnancy tests performed thereafter on such female patients in LAAM comprehensive maintenance treatment. Analysis of such tests shall be performed in a laboratory approved under the Clinical Laboratory Improvement Amendments of 1988 or in a laboratory certified by a State or private accrediting body approved by the Health Care Financing Administration.

(C) * * * For patients meeting these criteria, the quantity of take-home medication, if take-home medication is permitted for the narcotic drug, will be determined in the reasonable clinical judgment of the program physician, but in no case may the quantity of take-home medication be greater than would have been allowed at the time the patient voluntarily terminated previous treatment. * * *

(iv) *Special limitation; treatment of patients under 18 years of age.* (A) A person under 18 years of age is required to have had two documented attempts at short-term detoxification or drug-free treatment to be eligible for maintenance treatment, except as provided in paragraph (d)(1)(iv)(B) of this section. A 1-week waiting period is required after such a detoxification attempt, however, before an attempt is repeated. The program physician shall document in the patient's record that the patient continues to be or is again physiologically dependent on narcotic drugs. No person under 18 years of age may be admitted to a maintenance treatment program unless a parent, legal guardian, or responsible adult designated by the State authority (e.g., "emancipated minor" laws) completes and signs consent form, Form FDA–2635 "Consent to Treatment with an Approved Narcotic Drug."

(B) A person under 18 years of age shall not be admitted to LAAM maintenance treatment.

* * * * *

(3) * * * (i) * * * A pregnancy test is required for any woman of childbearing potential before she may be administered LAAM as directed in paragraph (d)(1)(iii)(B)(*1*) of this section.

* * *

* * * * *

(4) * * *

(v) *Authorized dispensers of narcotic drugs; responsibility.* A narcotic drug may be administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to order narcotic drugs for patients, or by an agent of such a practitioner, supervised by and under the order of the practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other health care professional authorized by Federal and State law to administer or dispense narcotic drugs. The licensed practitioner assumes responsibility for the amounts of narcotic drugs administered or dispensed and shall record and countersign all changes in dosage schedule.

* * * * *

(6) *Use of methadone in a treatment program; frequency of attendance; quantity of take-home medication; dosage of methadone; initial and stabilization*—(i) *Dosage and responsibility.* * * *

(ii) [Reserved]

* * * * *

(13) * * *

(i) * * * This system is required to comply with all Federal and State reporting requirements relevant to narcotic drugs approved for use in treatment of narcotic addiction. * * *

* * * * *

(h) *Denial or revocation of approval.* (1) Complete or partial denial or revocation of approval of an application

to receive shipments of narcotic drugs (Forms FDA–2632 "Application for Approval of Use of Narcotic Drugs in a Treatment Program" and FDA–2636 "Hospital Request for Methadone Detoxification Treatment") may be proposed to the Commissioner of Food and Drugs by the Director of the Food and Drug Administration's Center for Drug Evaluation and Research, on his or her own initiative or at the request of representatives of the Drug Enforcement Administration, Department of Justice, National Institute of Drug Abuse, the State authority, or any other interested person.

* * * * *

(k) *Use of narcotics other than methadone in a treatment program.* Narcotic drug products other than methadone that have been approved for treatment of narcotic addiction are listed in paragraph (b)(2)(v) of this section. Detailed information on the conditions for use of narcotic drug products other than methadone, with the exception of take-home and dosage form requirements, can be found in the respective approved product labeling. Treatment programs shall review the most recent approved product labeling for up-to-date information on important treatment parameters for each drug. Deviation from doses, frequencies, and conditions of usage described in the approved labeling shall be justified in the patient's record. Treatment programs that dispense narcotics other than methadone shall conform with the requirements set forth under paragraphs (a), (b), (c), (d)(1) through (d)(5), (d)(8) through (d)(14), and (e) through (l) of this section. Specifics regarding take-home and dosage form requirements along with any additional requirements are set forth in this paragraph.

(1) *LAAM*—(i) *Dosage and responsibility for administration.* After a patient's tolerance to LAAM is established, LAAM shall be administered no more frequently than every other day. Dosage of LAAM shall be individualized at doses, frequencies, and under conditions of usage described in approved labeling and as follows:

(A) *New patients.* The persons responsible for the program shall ensure that the initial dose of LAAM to a patient whose tolerance for the drug is unknown does not exceed 40 milligrams.

(B) *Stabilized methadone maintenance patient.* The persons responsible for the program shall ensure that the initial dose of LAAM for a previously stabilized methadone maintenance patient is less than or equal to 1.3 times the patient's daily methadone dose, not to exceed 120 milligrams.

(C) A licensed physician shall assume responsibility for the amount of the narcotic drug administered or dispensed and shall record, date, and sign or countersign in each patient's record each change in dosage schedule.

(D) The administering licensed physician shall ensure that a single dose of LAAM greater than 140 milligrams is justified in the patient's record.

(ii) *Dosage form.* LAAM may be administered in oral form when used in a maintenance treatment program. Hospitalized patients under care for a medical or surgical condition are permitted to receive LAAM in oral form when the attending physician judges it advisable. Although syrup concentrate or other formulations may be distributed to the program, all oral medication is required to be administered in a liquid formulation. Clinics that administer both LAAM and methadone shall take appropriate measures, including contrasting color and taste, to ensure that dosage forms of LAAM and methadone are easily distinguished.

(iii) *Take-home medication.* Take-home doses of LAAM are not permitted. A patient who is eligible for one or more take-home doses of methadone under paragraph (d)(6) of this section and who is unable to conform to the applicable mandatory LAAM dosing schedule because of exceptional circumstances such as illness, personal or family crises, travel, or other hardship, or official State holidays, may be temporarily transferred to methadone. Take-home doses of methadone for a patient eligible for a planned temporary discontinuation of treatment with LAAM shall be individualized at doses, frequencies, and under conditions of usage described in the approved labeling and the applicable provisions for take-home methadone medication under paragraph (d)(6) of this section. The maximum number of take-home doses of methadone shall be determined in accordance with the provisions of 21 CFR 291.505(d)(6)(v) and (d)(6)(vi).

(2) [Reserved]

(l) *Program forms.* The program sponsor must ensure that the following forms are completed by the proper program staff and submitted to the appropriate State authority and the Division of Scientific Investigations, Regulatory Management Branch (HFD–342), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855. The sponsor will indicate on the appropriate form which treatment drug is being utilized. Forms are available upon request from the Regulatory Management Branch (HFD–342) at the same address.

FORMS

FDA–2632 Application for Approval of Use of Narcotic Drugs in a Treatment Program.
FDA–2633 Medical Responsibility Statement for Use of Narcotic Drugs in a Treatment Program.
FDA–2635 Consent to Treatment with an Approved Narcotic Drug.
FDA–2636 Hospital Request for Methadone Detoxification Treatment.

(Approved by the Office of Management and Budget under number 0910–0140.)

Michael R. Taylor,

Deputy Commissioner for Policy.

Dated: April 8, 1993.

Richard A. Millstein,

Acting Director, National Institute on Drug Abuse.

[FR Doc. 93-17134 Filed 7–19–93; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF EDUCATION

34 CFR Parts 608 and 609

RIN 1840–AB74

Strengthening Historically Black Colleges and Universities Program and Strengthening Historically Black Graduate Institutions Program

AGENCY: Department of Education.

ACTION: Final regulations.

SUMMARY: The Secretary amends the regulations governing the Strengthening Historically Black Colleges and Universities Program and the Strengthening Historically Black Graduate Institutions Program, each of which is authorized under Title III of the Higher Education Act of 1965, as amended (HEA). The regulations are needed to implement changes made to Title III of the HEA by the Higher Education Amendments of 1992. These programs provide grants to assist eligible institutions in strengthening their physical plants, academic resources, and student services so that they may continue to participate in fulfilling the goal of equality of educational opportunity.

EFFECTIVE DATE: These regulations take effect either 45 days after publication in the **Federal Register** or later if the Congress takes certain adjournments. If you want to know the effective date of these regulations, call or write the Department of Education contact person. A document announcing the effective date will be published in the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Elwood L. Bland, U.S. Department of

Education, 400 Maryland Avenue SW., room 3042, ROB–3, Washington, DC 20202–5336. Telephone: (202) 708–9926. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Strengthening Historically Black Colleges and Universities (HBCU) Program and Strengthening Historically Black Graduate Institutions Program provide grants to assist eligible institutions in strengthening their physical plants, academic resources, and student services so that they may continue to participate in fulfilling the goal of equality of educational opportunity.

These programs address National Education Goal 5, which states that every adult American will possess the knowledge and skills necessary to compete in a global economy and assume the responsibilities of citizenship. The program furthers Goal 5 by assisting institutions in establishing and strengthening their physical plants, academic resources, and student services so that these institutions can provide equal educational opportunities for all adult Americans.

The major statutory change that is being incorporated into both regulations is the requirement that each institution applying for funds submit a comprehensive development plan describing its goals for financial management and academic programs and how the institution intends to achieve those goals. Other statutory changes that apply to both programs include the expansion of the type of allowable activities that may be carried out under a grant.

Other statutory changes that apply only to the HBCU program include the raising of the minimum grant from $350,000 to $500,000, and a change in the formula for allotting funds among eligible institutions. Under the latter change, 25 percent of each year's HBCU appropriation is allotted to eligible institutions based upon the relationship between the percentage of graduates of an eligible institution who, within five years of graduating with baccalaureate degrees, are attending graduate or professional schools and are enrolled in degree programs in disciplines in which Blacks are underrepresented, and the percentage of such graduates in all eligible institutions. The following explains how funds will be allotted to institutions under this latter change using fiscal year 1994 funds as an example.

For fiscal year 1994, October 1, 1993 through September 30, 1994, the relevant school year for attending graduate or professional school and being enrolled in relevant degree programs will be school year 1992–93. Thus, each eligible institution will report the number of its graduates who attended a graduate or professional school during school year 1992–93, enrolled in a degree program in a discipline in which Blacks are underrepresented at that school during that school year, and received a baccalaureate degree during any of the five preceding school years, i.e., school years 1987–88, 1988–89, 1989–90, 1990–91, and 1991–92. The institution will also report the number of its graduates who received a baccalaureate degree during 1987–88, 1988–89, 1989–90, 1990–91, and 1991–92. (In order for a junior or community college to report its graduates in this formula, it must determine which of its graduates obtained a baccalaureate degree at a four-year institution during the school years 1987–88 through 1991–92, and which of those graduates enrolled in the relevant programs in graduate or professional school during school year 1992–93.)

The Secretary divides the first number reported by the institution by the second reported number to obtain a percentage for that institution. The Secretary calculates a percentage for each reporting institution, obtains a sum of all the percentages, and divides each institution's percentage by the sum of the percentages. The Secretary then multiplies that resulting number by 25 percent of the fiscal year 1994 HBCU appropriation to obtain that institution's allotment.

In the Strengthening Historically Black Graduate Institutions Program, the changes include the addition of 11 graduate and professional institutions or programs to the previous five eligible grantee institutions, and a change in the funding of these institutions. In general, the new institutions receive funds under this program only if the annual appropriation for the program exceeds $12 million.

On February 23, 1993, the Secretary published a notice of proposed regulations for this program in the **Federal Register**, (58 FR 11158). There are no differences between the NPRM and these final regulations except for the statutory changes explained above.

Public Comment

In the NPRM the Secretary invited comments on the proposed regulations concerning the comprehensive development plan. The Secretary did not receive any comments.

Executive Order 12291

These regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Assessment of Educational Impact

In the notice of proposed rulemaking, the Secretary requested comments on whether the proposed regulations would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Based on the response to the proposed rules and on its own review, the Department has determined that the regulations in this document do not require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

Waiver of Proposed Rulemaking

In addition to the changes made to 34 CFR parts 608 and 609 that were subject to public comment in a notice of proposed rulemaking, the Secretary has revised the regulations to implement statutory changes made to each program by the Higher Education Amendments of 1992 (Pub. L. 102–325).

It is the practice of the Secretary to offer interested parties the opportunity to comment on proposed regulations in accordance with section 431(b)(2)(A) of the General Education Provisions Act (20 U.S.C. 1232(b)(2)(A)) and the Administrative Procedure Act (5 U.S.C. 553). However, since these revisions merely incorporate statutory changes into the regulations and do not implement substantive policy, public comment could have no effect. Therefore, the Secretary has determined pursuant to 5 U.S.C. 553(b)(B) that

further public comment on the regulations is unnecessary and contrary to the public interest.

List of Subjects in 34 CFR Parts 608 and 609

Colleges and universities, Grant programs—education, Reporting and recordkeeping requirements.

(Catalog of Federal Domestic Assistance Number: 84.031B Strengthening Historically Black Colleges and Universities Program and Strengthening Historically Black Graduate Institutions Program)

Dated: July 9, 1993.

Richard W. Riley,

Secretary of Education.

The Secretary amends Title 34 of the Code of Federal Regulations by revising parts 608 and 609 to read as follows:

PART 608—STRENGTHENING HISTORICALLY BLACK COLLEGES AND UNIVERSITIES PROGRAM

Subpart A—General

Sec.

Authority: 20 U.S.C. 1060 through 1063a, 1063c, 1066, 1068, 1069c, 1069d, and 1069f, unless otherwise noted.

Subpart A—General

§ 608.1 What is the Strengthening Historically Black Colleges and Universities (HBCU) Program?

The Strengthening Historically Black Colleges and Universities Program, hereafter called the HBCU Program, provides grants to Historically Black Colleges and Universities (HBCUs) to assist these institutions in establishing and strengthening their physical plants, academic resources and student services so that they may continue to participate in fulfilling the goal of equality of educational opportunity.

(Authority: 20 U.S.C. 1060)

§ 608.2 What institutions are eligible to receive a grant under the HBCU Program?

(a) To be eligible to receive a grant under this part, an institution must—

(1) Satisfy section 322(2) of the Higher Education Act of 1965, as amended (HEA);

(2) Be legally authorized by the State in which it is located—

(i) To be a junior or community college; or

(ii) To provide an educational program for which it awards a bachelor's degree; and

(3) Be accredited or preaccredited by a nationally recognized accrediting agency or association.

(b) The Secretary has determined that the following institutions satisfy section 322(2) of the HEA.

Alabama

Alabama A&M University-Huntsville
Alabama State University—Montgomery
Carver State Technical College—Mobile
Concordia College—Selma
Fredd State Technical College—Tuscaloosa
J.F. Drake State Technical College—Huntsville
S.D. Bishop State Junior College—Mobile
Lawson State College—Birmingham
Miles College—Birmingham
Oakwood College—Huntsville
Selma University—Selma
Stillman College—Tuscaloosa
Talladega University—Talladega
Trenholm State Technical College—Montgomery
Tuskegee University—Tuskegee

Arkansas

Arkansas Baptist College—Little Rock
Philander Smith College—Little Rock
Shorter College—Little Rock
University of Arkansas at Pine Bluff—Pine Bluff

Delaware

Delaware State College—Dover

District of Columbia

Howard University
University of the District of Columbia

Florida

Bethune Cookman College—Daytona Beach
Edward Waters College—Jacksonville
Florida A&M University—Tallahassee
Florida Memorial College—Miami

Georgia

Albany State College—Albany
Atlanta University—Atlanta
Clark College—Atlanta
Fort Valley State College—Fort Valley
Interdenominational Theological Center—Atlanta
Morehouse College—Atlanta
Morris Brown College—Atlanta
Paine College—Augusta
Savannah State College—Savannah
Spelman College—Atlanta

Kentucky

Kentucky State University—Frankfurt

Louisiana

Dillard University—New Orleans
Grambling State University—Grambling
Southern University A&M College—Baton Rouge
Southern University at New Orleans—New Orleans
Southern University at Shreveport—Shreveport
Xavier University of Louisiana—New Orleans

Maryland

Bowie State College—Bowie
Coppin State College—Baltimore
Morgan State University—Baltimore
University of Maryland-Eastern Shore—Princess Anne

Michigan

Lewis College of Business—Detroit

Mississippi

Alcorn State University—Lorman
Coahoma Junior College—Clarksdale
Jackson State University—Jackson
Mary Holmes College—West Point
Mississippi Valley State University—Itta Bena
Prentiss Normal and Industrial Institute—Prentiss
Rust College—Holly Springs
Tougaloo College—Tougaloo
Hinds Junior College (Utica Jr Coll)—Raymond

Missouri

Lincoln University—Jefferson City
Harris-Stowe State College—St. Louis

North Carolina

Barber-Scotia College—Concord
Bennett College—Greensboro
Elizabeth City State University—Elizabeth City
Fayetteville State University—Fayetteville
Johnson C. Smith University—Charlotte
Livingstone College—Salisbury
North Carolina A&T State University—Greensboro
North Carolina Central University—Durham
Saint Augustine's College—Raleigh
Shaw University—Raleigh
Winston-Salem State University—Winston Salem

Ohio

Central State University—Wilberforce
Wilberforce University—Wilberforce

Oklahoma

Langston University—Langston

Pennsylvania

Cheyney State University—Cheyney
Lincoln University—Lincoln

South Carolina

Allen University—Columbia
Benedict College—Columbia
Claflin College—Orangeburg
Clinton Junior College—Rock Hill
Denmark Technical College—Denmark
Morris College—Sumter
South Carolina State College—Orangeburg
Voorhees College—Denmark

Tennessee

Fisk University—Nashville
Knoxville College—Knoxville
Lane College—Jackson
LeMoyne-Owen College—Memphis
Meharry Medical College—Nashville
Morristown College—Morristown
Tennessee State University—Nashville

Texas

Huston-Tillotson College—Austin
Jarvis Christian College—Hawkins
Paul Quinn College—Waco
Prairie View A&M University—Prairie View
Saint Philip's College—San Antonio
Southwestern Christian College—Terrell
Texas College—Tyler
Texas Southern University—Houston
Wiley College—Marshall

U.S. Virgin Islands

College of the Virgin Islands—St. Thomas

Virginia

Hampton University—Hampton
Norfolk State University—Norfolk
Saint Paul's College—Lawrenceville
Virginia State University—Petersburg
Virginia Union University—Richmond

West Virginia

Bluefield State College—Bluefield
West Virginia State College—Institute

(c) If an institution identified in paragraph (b) of this section has merged with another institution, and, as a result of the merger, would not otherwise qualify to receive a grant under this part, that institution may nevertheless qualify to receive a grant under this part if—

(1) The institution would have qualified to receive a grant before the merger; and

(2) The institution was eligible to receive a grant under the Special Needs Program in any fiscal year prior to fiscal year 1986. (The Special Needs Program was authorized under Title III, Part B, of the HEA before 1986.)

(d) For the purpose of paragraph (a)(3) of this section, the Secretary publishes a list in the **Federal Register** of nationally recognized accrediting agencies and associations.

(e) Notwithstanding any other provision of this section, for each fiscal year—

(1) The University of the District of Columbia is eligible to receive a grant under this part only if the amount of the grant it is scheduled to receive under § 608.31 exceeds the amount it is scheduled to receive in the same fiscal year under the District of Columbia Self-Government and Governmental Reorganization Act; and

(2) Howard University is eligible to receive a grant under this part only if the amount of the grant it is scheduled to receive under § 608.31 exceeds the amount it is scheduled to receive in the same fiscal year under the Act of March 2, 1867, 20 U.S.C. 123.

(Authority: 20 U.S.C. 1061, 1063, and 1063a; House Report 99–861, 99th Cong., 2d Sess. p. 367, September 22, 1986; Senate Report 99–296, 99th Cong., 2d Sess. p. 23, May 12, 1986; Cong. Rec. of June 3, 1986, pp. 6588–6589)

§ 608.3 What regulations apply?

The following regulations apply to this part:

(a) The Department of Education General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations).

(2) The following sections of 34 CFR part 75 (Direct Grant Programs): §§ 75.1–75.104, 75.125–75.129, 75.190–75.192, 75.230–75.261, 75.500, 75.510–75.519, 75.524–75.534, 75.580–75.903, and 75.910;

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 82 (New Restrictions on Lobbying).

(6) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(7) 34 CFR part 86 (Drug-Free Schools and Campuses).

(b) The regulations in this part 608.

(Authority: 20 U.S.C. 1060–1063a, 1063c)

§ 608.4 What definitions apply?

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1:

Applicant
Application
Award
Budget
EDGAR
Equipment
Fiscal year
Grant period
Private
Project period
Public
Secretary

(b) *Other definitions.* The following definitions also apply to this part:

Accredited means the status of public recognition which a nationally recognized accrediting agency or association grants to an institution which meets certain established qualifications and educational standards.

Graduate means a student who has attended an institution for at least three semesters and fulfilled academic requirements for undergraduate studies in not more than five consecutive school years.

Junior or community college means an institution of higher education that—

(i) Admits as regular students persons who are beyond the age of compulsory school attendance in the State in which the institution is located and who have the ability to benefit from the training offered by the institution;

(ii) Does not provide an educational program for which it awards a bachelor's degree or an equivalent degree; and

(iii) Provides an educational program of not less than 2 years that is acceptable for full credit toward such a degree; or offers a 2-year program in engineering, mathematics, or the physical or biological sciences, designed to prepare a student to work as a technician or at the semiprofessional level in engineering, scientific, or other technological fields requiring the understanding and application of basic engineering, scientific, or mathematical principles of knowledge.

Pell Grant means the grant program authorized by Title IV–A–1 of the Higher Education Act of 1965, as amended.

Preaccredited means a status, also called candidacy status, that a nationally recognized accrediting agency or association, recognized by the Secretary to grant that status, has accorded an unaccredited institution that is making reasonable progress toward accreditation.

School year means the period of time from July 1 of one calendar year through June 30 of the subsequent calendar year. (A "school year" is equivalent to an "award year" under the Pell Grant Program.)

(Authority: 20 U.S.C. 1060–1063)

Subpart B—What Kind of Projects Does the Secretary Fund?

§ 608.10 What activities may be carried out under a grant?

(a) *Allowable activities.* Except as provided in paragraph (b) of this

section, a grantee may carry out the following activities under this part—

(1) Purchase, rental, or lease of scientific or laboratory equipment for educational purposes, including instructional or research purposes;

(2) Construction, maintenance, renovation, and improvement in classroom, library, laboratory, and other instructional facilities, including purchase or rental of telecommunications technology equipment or services;

(3) Support of faculty exchanges, faculty development and faculty fellowships to assist these faculty members in attaining advanced degrees in their fields of instruction;

(4) Academic instruction in disciplines in which Black Americans are underrepresented;

(5) Purchase of library books, periodicals, microfilm, and other educational materials, including telecommunications program materials;

(6) Tutoring, counseling, and student service programs designed to improve academic success;

(7) Funds and administrative management, and acquisition of equipment for use in strengthening funds management;

(8) Joint use of facilities, such as laboratories and libraries;

(9) Establishing or improving a development office to strengthen or improve contributions from alumni and the private sector;

(10) Establishing or enhancing a program of teacher education designed to qualify students to teach in a public elementary or secondary school in the State that shall include, as part of the program, preparation for teacher certification;

(11) Establishing community outreach programs that will encourage elementary and secondary students to develop the academic skills and the interest to pursue postsecondary education; and

(12) Other activities that it proposes in its application that contribute to carrying out the purpose of this part and are approved by the Secretary as part of the review and acceptance of the application.

(b) *Unallowable activities.* A grantee may not carry out the following activities under this part—

(1) Activities that are not included in the grantee's approved application;

(2) Activities described in paragraph (a)(12) of this section that are not approved by the Secretary;

(3) Activities that are inconsistent with any State plan of higher education that is applicable to the institution;

(4) Activities that are inconsistent with a State plan for desegregation of higher education that is applicable to the institution;

(5) Activities or services that relate to sectarian instruction or religious worship; and

(6) Activities provided by a school or department of divinity. For the purpose of this section, a "school or department of divinity" means an institution, or a department of an institution, whose program is specifically for the education of students to prepare them to become ministers of religion or to enter upon some other religious vocation, or to prepare them to teach theological subjects.

(c) No award under this part may be used for telecommunications technology equipment, facilities or services, if such equipment, facilities or services are available pursuant to section 396(k) of the Communications Act of 1934.

(Authority: 20 U.S.C. 1062, 1063a, and 1069c)

§ 608.11 What is the duration of a grant?

The Secretary may award a grant under this part for a period of up to five academic years.

(Authority: 20 U.S.C. 1063b(b))

Subpart C—How Does an Eligible Institution Apply for a Grant?

§ 608.20 What are the application requirements for a grant under this part?

In order to receive a grant under this part, an institution must submit an application to the Secretary at such time and in such manner as the Secretary may prescribe. The application must contain—

(a) A description of the activities to be carried out with grant funds;

(b) A description of how the grant funds will be used so that they will supplement and, to the extent practical, increase the funds that would otherwise be made available for the activities to be carried out under the grant and in no case supplant those funds;

(c) (1) A comprehensive development plan as described in § 608.21; or

(2) If an applicant has already submitted a comprehensive development plan as described in § 608.21, a description of the progress the applicant has made in carrying out the goals of its plan;

(d) An assurance that the institution will provide the Secretary with an annual report on the activities carried out under the grant;

(e) An assurance that the institution will provide for, and submit to the Secretary, the compliance and financial audit described in § 608.41;

(f) An assurance that the proposed activities in the application are in accordance with any State plan that is applicable to the institution;

(g) The number of graduates of the applicant institution during the school year immediately preceding the fiscal year for which grant funds are requested; and

(h) The number of graduates of the applicant institution—

(1) Who, within five years of graduating with baccalaureate degrees, attended graduate or professional schools and enrolled in degree programs in disciplines in which Blacks are underrepresented during the school year immediately preceding the fiscal year for which funds are requested; and

(2) Who graduated with baccalaureate degrees during any one of the five school years immediately preceding the school year described in paragraph (h)(1) of this section.

(Approved by the Office of Management and Budget under control number 1840–0113)

(Authority: 20 U.S.C. 1063, 1063a and 1066(b)(2))

§ 608.21 What is a comprehensive development plan and what must it contain?

(a) A comprehensive development plan must describe an institution's strategy for achieving growth and self-sufficiency by strengthening its—

(1) Financial management;

(2) Academic programs; and

(b) The comprehensive development plan must include the following:

(1) An assessment of the strengths and weaknesses of the institution's financial management and academic programs.

(2) A delineation of the institution's goals for its financial management and academic programs, based on the outcomes of the assessment described in paragraph (b)(1) of this section.

(3) A listing of measurable objectives designed to assist the institution to reach each goal with accompanying timeframes for achieving the objectives.

(4) A description of methods, processes, and procedures that will be used by the college or university to institutionalize financial management and academic program practices and improvements developed under the proposed funded activities.

(Approved by the Office of Management and Budget under control number 1840–0113)

(Authority: 20 U.S.C. 1063a)

Subpart D—How Does the Secretary Make a Grant?

§ 608.30 What is the procedure for approving and disapproving grant applications?

The Secretary—

(a) Approves any application that satisfies the requirements of § 608.10 and § 608.20; and

(b) Does not disapprove any application, or any modification of an application, without affording the applicant reasonable notice and opportunity for a hearing.

(Authority: 20 U.S.C. 1063a)

§ 608.31 How does the Secretary determine the amount of a grant?

(a) Except as provided in paragraph (c) of this section, for each fiscal year, the Secretary determines the amount of a grant under this part by-

(1) Multiplying fifty percent of the amount appropriated for the HBCU Program by the following fraction:

Number of Pell Grant recipients at the applicant institution during the school year immediately preceding that fiscal year.

Number of Pell Grant recipients at all applicant institutions during the school year immediately preceding that fiscal year.

(2) Multiplying twenty-five percent of the amount appropriated for the HBCU Program by the following fraction:

Number of graduates of the applicant institution during the school year immediately preceding that fiscal year.

Number of graduates of all applicant institutions during the school year immediately preceding that fiscal year.

(3) Multiplying twenty-five percent of the amount appropriated for the HBCU Program by the following fraction:

The percentage of graduates of an applicant institution who, within five years of graduating with baccalaureate degrees, are in attendance at graduate or professional schools and enrolled in degree programs in disciplines in which Blacks are underrepresented

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The sum of the percentages of those graduates of all applicant institutions.

(4) Adding the amounts obtained in paragraphs (a)(1), (a)(2), and (a)(3) of this section.

(b)(1) For each fiscal year, the numerator in paragraph (a)(3) of this section is calculated by—

(i) Determining the number of graduates of an applicant institution who, within five years of graduating with baccalaureate degrees, attended graduate or professional schools and enrolled in degree programs in disciplines in which Blacks are underrepresented during the school year immediately preceding that fiscal year; and

(ii) Dividing the number obtained in paragraph (b)(1)(i) of this section by the number of graduates of an applicant institution who graduated with baccalaureate degrees during the five school years immediately preceding the school year described in paragraph (b)(1)(i) of this section.

(2) For purposes of this section, the Secretary—

(i) Considers that Blacks are underrepresented in a professional or academic discipline if the percentage of Blacks in that discipline is less than the percentage of Blacks in the general population of the United States; and

(ii) Notifies applicants of the disciplines in which Blacks are underrepresented through a notice in the **Federal Register**, after consulting with the Commissioner of the Bureau of Labor Statistics.

(c) Notwithstanding the formula in paragraph (a) of this section—

(1) For each fiscal year, each eligible institution with an approved application must receive at least $500,000; and

(2) If the amount appropriated for a fiscal year for the HBCU Program is insufficient to provide $500,000 to each eligible institution with an approved application, each grant is ratably reduced. If additional funds become available for the HBCU Program during a fiscal year, each grant is increased on the same basis as it was decreased until the grant amount reaches $500,000.

(d) The amount of any grant that the Secretary determines will not be required by a grantee for the period for which the grant was made is available for reallotment by the Secretary during that period to other eligible institutions under the formula contained in paragraph (a) of this section.

(Authority: 20 U.S.C. 1063)

Subpart E—What Conditions Must a Grantee Meet?

§ 608.40 What are allowable costs and what are the limitations on allowable costs?

(a) *Allowable costs.* Except as provided in paragraphs (b) and (c) of this section, a grantee may expend grant funds for activities that are related to carrying out the allowable activities included in its approved application.

(b) *Supplement and not supplant.* Grant funds shall be used so that they supplement, and to the extent practical, increase the funds that would otherwise be available for the activities to be carried out under the grant, and in no case supplant those funds.

(c) *Limitations on allowable costs.* A grantee may not—

(1) Spend more than fifty percent of its grant award in each fiscal year for costs relating to constructing or maintaining a classroom, library, laboratory, or other instructional facility; or

(2) Use an indirect cost rate to determine allowable costs under its grant.

(Authority: 20 U.S.C. 1062 and 1066)

§ 608.41 What are the audit and repayment requirements?

(a) (1) A grantee shall provide for the conduct of a compliance and financial audit of any funds it receives under this part of a qualified, independent organization or person in accordance with the *Standards for Audit of Governmental Organizations, Programs, Activities, and Functions*, 1981 revision, established by the Comptroller General of the United States. This publication is available from the Superintendent of Documents, U.S. Government Printing Office.

(2) The grantee shall have an audit conducted at least once every two years, covering the period since the previous audit, and the grantee shall submit the audit to the Secretary.

(3) If a grantee is audited under Chapter 75 of Title 31 of the United States Code, the Secretary considers that audit to satisfy the requirements of paragraph (a)(1) of this section.

(b) An institution awarded a grant under this part must submit to the Department of Education Inspector General three copies of the audit required in paragraph (a) of this section within six months after completion of the audit.

(c) Any individual or firm conducting an audit described in this section shall give the Department of Education's Inspector General access to records or other documents necessary to review the results of the audit.

(d) A grantee shall repay to the Treasury of the United States any grant funds it received that it did not expend or use to carry out the allowable activities included in its approved application within ten years following the date of the initial grant it received under this part.

(Authority: 20 U.S.C. 1063a and 1063c)

§ 608.42 Under what conditions does the Secretary terminate a grant?

The Secretary terminates any grant under which funds were not expended if an institution loses—

(a) Its accredited status; or

(b) Its legal authority in the State in which it is located—

(1) To be a junior or community college; or

(2) To provide an educational program for which it awards a bachelor's degree.

(Authority: 20 U.S.C. 1063a)

PART 609—STRENGTHENING HISTORICALLY BLACK GRADUATE INSTITUTIONS PROGRAM

Subpart A—General

Subpart B—What Kind of Project Does the Secretary Fund?

Subpart C—How Does an Eligible Institution Apply for a Grant?

Subpart D—How Does the Secretary Make a Grant?

Subpart E—What Conditions Must a Grantee Meet?

Authority: 20 U.S.C. 1063b and 1063c, unless otherwise noted.

Subpart A—General

§ 609.1 What is the Strengthening Historically Black Graduate Institutions Program?

The Strengthening Historically Black Graduate Institutions Program provides grants to the institutions listed in § 609.2 to assist these institutions in establishing and strengthening their physical plants, development offices, endowment funds, academic resources and student services so that they may continue to participate in fulfilling the goal of equality of educational opportunity in graduate education.

(Authority: 20 U.S.C. 1060 and 1063b)

§ 609.2 What institutions are eligible to receive a grant under this part?

(a) An institution or an institution's qualified graduate program listed in paragraph (b) of this section is eligible to receive a grant under this part if the Secretary determines that the institution is making a substantial contribution to legal, medical, dental, veterinary or other graduate education opportunities for Black Americans.

(b) The institutions and programs referred to in paragraph (a) of this section are—

(1) Morehouse School of Medicine;
(2) Meharry Medical School;
(3) Charles R. Drew Postgraduate Medical School;
(4) Clark Atlanta University;
(5) Tuskegee Institute School of Veterinary Medicine;
(6) Xavier University School of Pharmacy;
(7) Southern University School of Law;
(8) Texas Southern University School of Law and School of Pharmacy;
(9) Florida A&M University School of Pharmaceutical Sciences;
(10) North Carolina Central University School of Law;
(11) Morgan State University's qualified graduate program;
(12) Hampton University's qualified graduate program;
(13) Alabama A&M's qualified graduate program;
(14) North Carolina A&T State University's qualified graduate program;
(15) University of Maryland Eastern Shore's qualified graduate program; and
(16) Jackson State University's qualified graduate program.

(c) An institution that was awarded a grant prior to October 1, 1992 may continue to receive grant payments, regardless of the eligibility of the graduate institutions described in paragraphs (b)(6) through (16) of this section, until the institution's grant period has expired or September 30, 1993, whichever is later.

(d) No institution of higher education or university system may receive more than one grant under this section in any fiscal year.

(Authority: 20 U.S.C. 1063b(e))

§ 609.3 What regulations apply?

The following regulations apply to this part:

(a) The Department of Education General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations).

(2) The following sections of 34 CFR part 75 (Direct Grant Programs): §§ 75.1–75.104, 75.125–75.129, 75.190–75.192, 75.230–75.261, 75.500, 75.510–75.519, 75.524–75.534, 75.580–75.903, and 75.901;

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 82 (New Restrictions on Lobbying).

(6) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants))

(7) 34 CFR part 86 (Drug-Free Schools and Campuses).

(b) The regulations in this part 609.

(Authority: 20 U.S.C. 1063b)

§ 609.4 What definitions apply?

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 34 CFR 77.1:

Applicant
Application
Award
Budget
EDGAR
Equipment
Fiscal year
Grant period
Private
Project period
Public
Secretary

(b) The following definition applies to a term used in this part:

Qualified graduate program means a graduate or professional program that—

(i) Provides a program of instruction in the physical or natural sciences, engineering, mathematics, or other scientific disciplines in which African Americans are underrepresented;

(ii) Has been accredited or approved by a nationally recognized accrediting agency or association. (The Secretary publishes a list in the **Federal Register** of nationally recognized accrediting agencies and associations.); and

(iii) Has students enrolled in that program when the institution offering the program applies for a grant under this part.

(Authority: 20 U.S.C. 1063b and 1069c)

Subpart B—What Kind of Projects Does the Secretary Fund?

§ 609.10 What activities may be carried out under a grant?

(a) *Allowable activities.* Except as provided in paragraph (b) of this section, a grantee may carry out the following activities under this part—

(1) Purchase, rental, or lease of scientific or laboratory equipment for educational purposes, including instructional or research purposes;

(2) Construction, maintenance, renovation, and improvement in classroom, library, laboratory, and other instructional facilities, including

purchase or rental of telecommunications technology equipment or services;

(3) Support of faculty exchanges, faculty development and faculty fellowships to assist these faculty members in attaining advanced degrees in their fields of instruction;

(4) Academic instruction in disciplines in which Black Americans are underrepresented;

(5) Purchase of library books, periodicals, microfilm, and other educational materials, including telecommunications program materials;

(6) Tutoring, counseling, and student service programs designed to improve academic success;

(7) Funds and administrative management, and acquisition of equipment for use in strengthening funds management;

(8) Joint use of facilities, such as laboratories and libraries;

(9) Establishing or improving a development office to strengthen or improve contributions from alumni and the private sector;

(10) Establishing or enhancing a program of teacher education designed to qualify students to teach in a public elementary or secondary school in the State that shall include, as part of such program preparation for teacher certification;

(11) Establishing community outreach programs that will encourage elementary and secondary students to develop the academic skills and the interest to pursue postsecondary education;

(12) Other activities that it proposes in its application that contribute to carrying out the purpose of this part and are approved by the Secretary;

(13) Establishing or improving a development office to strengthen and increase contributions from alumni and the private sector; and

(14) Establishing and maintaining an institutional endowment under 34 CFR part 628 to facilitate financial independence.

(b) *Unallowable activities.* A grantee may not carry out the following activities under this part—

(1) Activities that are not included in the grantee's approved application;

(2) Activities described in paragraph (a)(12) of this section that are not approved by the Secretary;

(3) Activities that are inconsistent with any State plan of higher education that is applicable to the institution;

(4) Activities that are inconsistent with a State plan for desegregation of higher education that is applicable to the institution;

(5) Activities or services that relate to sectarian instruction or religious worship; and

(6) Activities provided by a school or department of divinity. For the purpose of this section, a "school or department of divinity" means an institution, or a department of an institution, whose program is specifically for the education of students to prepare them to become ministers of religion or to enter upon some other religious vocation, or to prepare them to teach theological subjects.

(c) No award under this part may be used for telecommunications technology equipment, facilities or services, if such equipment, facilities or services are available pursuant to section 396(k) of the Communications Act of 1934.

(Authority: 20 U.S.C. 1062, 1063a, and 1069c)

§ 609.11 What is the duration of a grant?

The Secretary may award a grant under this part for a period of up to five academic years.

(Authority: 20 U.S.C. 1063b(b))

Subpart C—How Does an Eligible Institution Apply for a Grant?

§ 609.20 What are the application requirements for a grant under this part?

In order to receive a grant under this part, an institution must submit an application to the Secretary at such time and in such manner as the Secretary may prescribe. The application must contain—

(a) A description of the activities to be carried out with grant funds and how those activities will improve graduate educational opportunities for Black and low-income students and lead to greater financial independence for the applicant;

(b) A description of how the applicant is making a substantial contribution to the legal, medical, dental, veterinary or other graduate education opportunities for Black Americans;

(c) An assurance from each applicant requesting in excess of $500,000 that 50 percent of the costs of all the activities to be carried out under the grant will come from non-Federal sources;

(d) A description of how the grant funds will be used so that they will supplement, and to the extent practical, increase the funds that would otherwise be made available for the activities to be carried out under the grant and in no case supplant those funds, for the activities described in § 609.10(a)(1) through § 609.10(a)(14);

(e) An assurance that the proposed activities in the application are in accordance with any State plan that is applicable to the institution; and

(f)(1) A comprehensive development plan as described in § 609.21; or

(2) If an applicant has already submitted a comprehensive development plan as described in § 609.21, a description of the progress the applicant has made in carrying out the goals of its plan.

(Approved by the Office of Management and Budget under control number 1840–0113)

(Authority: 20 U.S.C. 1063d and 1066(b)(2))

§ 609.21 What is a comprehensive development plan and what must it contain?

(a) A comprehensive development plan must describe an institution's strategy for achieving growth and self-sufficiency by strengthening its—

(1) Financial management;

(2) Academic programs; and

(b) The comprehensive development plan must include the following:

(1) An assessment of the strengths and weaknesses of the institution's financial management and academic programs.

(2) A delineation of the institution's goals for its financial management and academic programs, based on the outcomes of the assessment described in paragraph (b)(1) of this section.

(3) A listing of measurable objectives designed to assist the institution to reach each goal with accompanying timeframes for achieving the objectives.

(4) A description of methods, processes and procedures that will be used by the college or university to institutionalize financial management and academic program practices and improvements developed under the proposed funded activities.

(Approved by the Office of Management and Budget under control number 1840–0113)

(Authority: 20 U.S.C. 1063a)

Subpart D—How Does the Secretary Make a Grant?

§ 609.30 What is the procedure for approving and disapproving grant applications?

The Secretary approves any application that satisfies the requirements of § 609.10 and § 609.20.

(Authority: 20 U.S.C. 1063a)

§ 609.31 How does the Secretary determine the amount of a grant?

Of the amount appropriated for any fiscal year—

(a)(1) The first $12,000,000 (or any lesser amount appropriated) shall be available only for the purpose of making grants to institutions or programs described in § 609.2(b)(1) through § 609.2(b)(5);

(2) If the sum of the approved applications does not exceed the amount appropriated, the Secretary awards grants in the amounts requested and approved;

(3) If the sum of the approved requests exceeds the sum appropriated, and Morehouse School of Medicine submits an approved request for at least $3,000,000, and the amount appropriated exceeds $3,000,000, the Secretary awards no less than $3,000,000 to Morehouse School of Medicine and reduces the grants to the institutions described in § 609.2(b)(1) through § 609.2(b)(5) as the Secretary considers appropriate, so that the sum of the approved grants equals the amount appropriated; and

(4) If Morehouse School of Medicine submits an approved request for at least $3,000,000 and the amount appropriated does not exceed $3,000,000, Morehouse School of Medicine receives all the appropriated funds; and

(b)(1) Any amount appropriated in excess of $12,000,000 shall be available for the purpose of making grants, in equal amounts not to exceed $500,000, to institutions or programs described in § 609.2(b)(6) through § 609.2(b)(16); and

(2) If any funds remain, the Secretary makes grants to institutions or programs described in § 609.2(b)(1) through § 609.2(b)(16).

(Authority: 20 U.S.C. 1063b)

Subpart E—What Conditions Must a Grantee Meet?

§ 609.40 What are the matching requirements?

If an institution receives a grant in excess of $500,000, it must spend non-Federal funds to meet the cost of at least 50 percent of the activities approved in its application.

(Authority: 20 U.S.C. 1063b)

§ 609.41 What are allowable costs and what are the limitations on allowable costs?

(a) *Allowable costs.* Except as provided in paragraphs (b) and (c) of this section, a grantee may expend grant funds for activities that are reasonably related to carrying out the allowable activities included in its approved application.

(b) *Supplement and not supplant.* A grantee shall use grant funds so that they supplement, and to the extent practical, increase the funds that would otherwise be available for the activities to be carried out under the grant, and in no case supplant those funds.

(c) *Limitations on allowable costs.* A grantee may not—

(1) Spend more than fifty percent of its grant award in each fiscal year for costs relating to constructing or maintaining a classroom, library, laboratory, or other instructional facility; and

(2) Use an indirect cost rate to determine allowable costs under its grant.

(Authority: 20 U.S.C. 1062, 1063b, and 1066)

§ 609.42 What are the audit and repayment requirements?

(a) (1) A grantee shall provide for the conduct of a compliance and financial audit of any funds it receives under this part by a qualified, independent organization or person in accordance with the Standards for Audit of Governmental Organizations, Programs, Activities, and Functions, 1981 revision, established by the Comptroller General of the United States. This publication is available from the Superintendent of Documents, U.S. Government Printing Office.

(2) The grantee shall have an audit conducted at least once every two years, covering the period since the previous audit, and the grantee shall submit the audit to the Secretary.

(3) If a grantee is audited under Chapter 75 of Title 31 of the United States Code, the Secretary considers that audit to satisfy the requirements of paragraph (a)(1) of this section.

(b) An institution awarded a grant under this part must submit to the Department of Education Inspector General three copies of the audit required in paragraph (a) of this section within six months after completion of the audit.

(c) Any individual or firm conducting an audit described in this section shall give the Department of Education's Inspector General access to records or other documents necessary to review the results of the audit.

(d) A grantee shall repay to the Treasury of the United States any grant funds it received that it did not expend or use to carry out the allowable activities included in its approved application within ten years following the date of the initial grant it received under this part.

(Authority: 20 U.S.C. 1063a)

§ 609.43 Under what conditions does the Secretary terminate a grant?

The Secretary terminates any grant under which funds were not expended if an institution loses—

(a) Its accredited status; or

(b) Its legal authority in the State in which it is located.

(Authority: 20 U.S.C. 1063a)

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Part 1

[Docket No. 920775–3145]

RIN 0651–AA44

Changes In Patent Drawing Standards

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Final rule.

SUMMARY: The Patent and Trademark Office (Office) is amending the rules of practice regarding patent drawings to adopt international standards and to eliminate unnecessary requirements. The Office is amending the rules to provide clarification and adopt international standards; to delete the reference to changes by bonded draftsmen since the Office will no longer release drawings from patent applications; and to include the option of submitting black and white photographs in lieu of black ink drawings.

EFFECTIVE DATE: October 1, 1993. These rules will be applicable to all drawings and papers filed with the Office on or after the effective date.

FOR FURTHER INFORMATION CONTACT: Richard A. Bawcombe by telephone at (703) 305–8594, by mail marked to his attention addressed to the Commissioner of Patents and Trademarks, Washington, DC 20231, or by facsimile transmission to his attention at (703) 305–4372.

SUPPLEMENTARY INFORMATION: In a Notice of Proposed Rulemaking published in the **Federal Register** (57 FR 42721) on September 16, 1992, and in the Patent and Trademark Office Official Gazette (1143 Off. Gaz. Pat. Office 13) on October 6, 1992, the Office proposed to amend the rules of practice in patent drawings. Drawings acceptable for patent applications filed outside of the United States are not always acceptable in a patent application filed in the United States. Therefore, the rules relating to drawing requirements are being amended to enable the Office, when appropriate, to accept drawings that are capable of clear reproduction for the printing of any resulting patent. Drawings in compliance with the old § 1.84 will be in compliance with the new § 1.84.

An oral hearing was not conducted. However, six written comments were submitted.

Response to Comments on the Rules

The comments received in response to the notice of proposed rulemaking have been given careful consideration and several of the suggested modifications have been adopted. Another modification, since the "Notice of Proposed Rulemaking," is under § 1.84 wherein five sets of drawings were required, but the total has been decreased to three sets due to a reassessment of the need for the additional copies for Office use. The comments and responses are discussed below.

Comment: Three comments were received regarding the proposed changes within § 1.84(b). Three other comments were received regarding the proposed changes to § 1.165. All six comments suggested that the Office continue to accept mounted photographs.

Response: The Office will adopt the suggestion and continue to accept mounted photographs for utility, design, and plant patent applications. The initial reason the Office sought to change the rule was to overcome the problem of mounted photographs becoming detached and separated from the file. The apparent burden to applicants associated with the Office not accepting mounted photographs is the reason the Office will continue to permit mounted photographs provided they are permanently affixed.

Several of the commenters mentioned that they have never had problems with mounted photographs. As commentary on these remarks, it is not the person filing the drawings who would have problems with mounted photographs; it is the Office. And, indeed, the Office has, in the past, experienced problems with mounted photographs coming loose from the paper they are mounted on. When this happens, the photographs can become displaced from the file and lost. This has occurred many times, leading to frustration and wasted effort on the part of many practitioners, as well as on the part of Office personnel. If mounted photographs are to be used, they must be mounted in such a way that they cannot become loose from the bristol board to which they are mounted.

Comment: Two of the comments regarding 1.84(b) also mentioned that the proposed rules would not allow more than one figure on each sheet of drawings where photographs are being used, and sought relief from this proposed change.

Response: Since the office will continue to accept mounted photographs, the Office will also accept sheets of drawings where more than one photograph appears on the drawing sheet provided that all other drawing requirements are met.

Comment: Two of the comments suggested that the Office not require photographs to be on A4 size paper.

Response: The Office will adopt the suggestion. The Office will accept photographs on one of the four paper sizes specified in § 1.84(f), as long as all sheets are the same size.

Comment: Regarding § 1.84(f), one comment suggested that the Office permit use of an additional size of paper, i.e., 21.6 cm. by 27.9 cm. (8½ by 11 inches).

Response: The Office will adopt the suggestion. The adoption of the suggestion to add an additional paper size under § 1.84(f), results in the need for an additional margin size. Therefore, an additional paragraph is added to § 1.84(g) to state that "On 21.6 cm. by 27.9 cm. (8½ by 11 inch) drawing sheets, each sheet must include a top margin of 2.5 cm. (1 inch) and bottom and side margins of .64 cm. (¼ inch) from the edges, thereby leaving a sight precisely 16.9 by 24.3 cm. (6$^{11}/_{16}$ by 9$^{9}/_{16}$ inches)."

Comment: Regarding 1.84 (p)(3), one comment suggested liberalization for drawings which include typewritten subject matter, such as gene or protein sequences that consist predominantly of letters, sometimes with underlining and boxes around them. Other situations cited were graphs and photographs of gels, which often appear in biotechnological inventions, which include typed matter as legends.

Response: The suggestion has not been adopted because letters need to stand at the designated height to maintain legibility when reductions become necessary to accommodate the various photocomposed products.

Comment: Regarding § 1.84(w), one comment mentioned that correction fluid is not permanent and has a tendency to flake and fall from the surface it covers.

Response: Section 1.84(w) permits correction fluid to be used provided the correction fluid is durable and permanent. If correction fluid is used on drawings submitted to the Office, the applicant will be required by the Office to correct the drawings if the correction fluid becomes loose before the patent printing process is completed.

Comment: One comment suggested that § 1.152 was improper in permitting either ink drawings or photographs to be submitted with an application for a design patent, but not both, and in requiring any photographs submitted to show only the design claimed and none of the environment in which it is used. The comment argued that prohibition against using both ink drawings and photographs is inconsistent with 35 U.S.C. 112. Under that section of the statute, a design patent application must disclose the invention "in such full, clear, concise, and exact terms as enable any person skilled in the art . . . to make and use" the invention and "set forth the best mode contemplated by the inventor of carrying out his invention."

Response: Section 1.152 is consistent with 35 U.S.C. 112. The introduction of both photographs and ink drawings in a design application would result in a high probability of inconsistencies between corresponding elements on the ink drawings as compared with the photographs. However, if special circumstances warrant use of both ink drawings and photographs, applicant can file a petition under § 1.183 to permit both in a design application if such drawings do not introduce inconsistencies between the views.

Discussion of Specific Sections Changed or Added

Section 1.17(h) is amended to include a reference to § 1.84 for accepting color drawings or photographs in utility patent applications.

Section 1.19(a)(3) is amended to change the citation of § 1.84(p) to § 1.84(a)(2) in view of the amendments to § 1.84.

Section 1.71(d) is amended to change the citation of § 1.84(o) to § 1.84(o) to § 1.84(s) in view of the amendments to § 1.84.

Section 1.84 is revised as follows:

(a) *Drawings.* This paragraph is added to classify drawings into two categories, i.e., black ink and color, and deletes the limitation that the use of white pigment to cover lines is not normally acceptable. The black ink drawing requirements are amended to allow computer-generated drawings to be accepted subject to the same standards applied to all black ink drawings. Color drawing requirements are moved from § 1.84(p) to § 1.84(a). Color drawings may be acceptable upon the granting of a petition filed under this paragraph explaining why the color drawings are necessary. A petition is required because the special handling necessary for color drawings is time consuming and the Office cannot permit such a special procedure except in extenuating circumstances. Since utility patents are not printed in color, 3 sets of color drawings are necessary for proper distribution within the Office. One color

set will be attached to the Letters Patent for routing to the applicant. The remaining two color sets will be routed to (1) the patent file, and (2) the Office of Publication and Dissemination, Patent and Trademark Copy Sales, for copying purposes when a copy in color of a utility patent containing a color drawing, as provided for in § 1.19(a)(3), is requested.

(b) *Photographs.* This paragraph permits the acceptance of photographs upon granting of an applicant's petition. The Office will accept black and white and color photographs or photomicrographs (not photolithographs or other reproductions of photographs made by using screens) developed on double weight photographic paper or permanently mounted on bristol board, in lieu of ink drawings. The photographs must be of sufficient quality so that all details in the drawing are reproducible in the print patent.

(c) *Identification of drawings.* This paragraph permits an applicant to provide proper identification information on the reverse side of each sheet of drawings. The identification information allows the Office to match drawing sheets with the proper application. The identification information should include the application number, if known, or the title of the invention, inventor's name, docket number (if any), and name and telephone number of the person to call if the drawings cannot be matched to the proper patent application. The Office will not object if identifying information is not present; however, if the drawings become separated, it will be virtually impossible for the Office to match the drawings with the application. This paragraph is restructured from previous § 1.84(1) and revised to state that the preferred placement of the information is on the back side of the drawings sheets.

(d) *Graphic forms in drawings.* This paragraph is added to set standards for chemical and mathematical formulae to align Office standards for formulae, tables, and waveforms with international standards.

(e) *Type of paper.* This paragraph is a revision of previous § 1.84(a) to set forth the requirements for the type of paper to be used for drawings, including the type of paper for photographs.

(f) *Size of paper.* This paragraph clarifies Office requirements set forth in previous § 1.84(b) and permits one additional size of paper, i.e., 21.6 cm. by 27.9 cm. (8½ by 11 inches) for drawings.

(g) *Margins.* This paragraph is restructured from previous § 1.84(b) to indicate how the size of the paper changes the margin requirements. The Office will accept four sizes of paper, however, the sight (i.e., the usable surface) is the same for two of the paper sizes, i.e., 21.6 cm. by 33.1 cm. (8½ by 13 inches), and 21.6 cm. by 35.6 cm. (8½ by 14 inches). The sight is 17.0 cm. by 26.2 cm. for DIN size A4 paper. The sight is 16.9 cm. by 24.3 cm. (6 11/16 by 9 9/16 inches) for the added paper size of 21.6 cm. by 27.9 cm. (8½ by 11 inches).

(h) *Views.* This paragraph is added to reformat previous § 1.84(i) to provide a logical arrangement of the different views provided in the rules, to revise the standards for purposes of clarification, to include the standard for waveforms to show the relative timing, to provide clearer language relative to hatching shown on drawings, to set forth the standard for depicting hatching in sectional views as regularly spaced parallel oblique strokes which precludes use of cross-hatching strokes, and to include requirements pertaining to alternate positions. In addition, both Roman and Arabic numerals are acceptable to designate the section being illustrated.

(i) *Arrangement of views.* This paragraph is relocated from previous § 1.84(j) and revised to incorporate international standards. In addition, this paragraph is changed and broadened to provide for placement of words on drawings. One view is not to be superimposed within the outline of another. The changes expand the possibilities for presenting graphs to conform to standard scientific conventions, while using a format which is compatible with automated patent searching displays. See 1121 Off. Gaz. Pat. Office 54 (Dec. 25, 1990) and 1129 Off. Gaz. Pat. Office 22 (Aug. 13, 1991).

(j) *View for Official Gazette.* This paragraph is relocated from previous § 1.84(k).

(k) *Scale.* This paragraph is relocated from previous § 1.84(e) and § 1.84(i) and revised to indicate that the words "actual size" or "scale ½" on the drawings are not permitted since the meaning is lost in reduction/enlargement. The paragraph provides that elements of the same view must be in proportion to each other, unless a difference in proportion is indispensable for the clarity of the view. As a preferred alternative to a difference in proportion within one view for the purpose of achieving the necessary clarity, a supplementary view may be added giving a larger-scale illustration of an element from the initial review. When a supplementary view is included, it is recommended that the enlarged element shown in the second view be surrounded by a finely drawn or "dot-dash" circle in the first view pinpointing its location, without obscuring the view.

(l) *Character of lines, numbers, and letters.* This paragraph is located from previous § 1.84(c) and revised to indicate that lines and strokes of different thicknesses may be used in the same drawing where different thicknesses have different meanings. In addition, this paragraph is changed and broadened to allow drawings to be made by any process which will give them satisfactory reproduction characteristics.

(m) *Shading.* This paragraph is changed and broadened to expand definitions for shading and deletes the limitation that drawings transmitted to the Office should be sent flat, protected by a sheet of heavy binder's board, or rolled for transmission in a suitable mailing tube. This change provides the individual practitioner with greater discretion on how to set drawings. In addition, this paragraph is relocated from previous § 1.84(d) to separate shading requirements from hatching requirements by stating that shading may be used to indicate the surface or shape of sherical, cylindrical, and economic elements of an object, and that space lines are preferred for shading purposes. Solid black areas are not permitted, except when used to represent bar graphs or color.

(n) *Symbols.* This paragraph is relocated from previous § 1.84(g) to separate symbols requirements from legends requirements and enlarges the number of acceptable symbols. Known devices should be illustrated by symbols which have a universally-recognized meaning, and which are generally accepted in the art, provided no further detail is essential for understanding the subject matter of the claimed invention. Symbols which are not universally recognized may be used if they are not likely to be confused with existing conventional symbols and if they are readily identifiable, subject to approval by the Examiner.

(o) *Legends.* This paragraph is relocated from previous § 1.84(g) to separate legends requirements from symbols requirements and revised to integrate international standards. Where text matter is (1) deemed indispensable for understanding the drawing or (2) may be required by the Examiner, a minimum of words should be used. While such requirement by the Examiner was not contained in the "Notice of Proposed Rulemaking," it was contained in former § 1.84(g). Words should not be used to describe the figure itself, such as "this is a bar

graph." All text legends are subject to approval by the examiner.

(p) *Numbers, letters, and reference characters.* This paragraph is relocated from previous § 1.84(f) and revised to include numbers and letters in the heading formerly designated "reference characters." This section has been reformatted into five subsections and revised to integrate international standards, where possible. Although the Latin alphabet is used in the international standard, the Office takes the view that the English alphabet is more universally acceptable for letters, except where another alphabet is customarily used, such as the Greek alphabet to indicate angles, wavelengths, and mathematical formulae. In addition, the characters used must be oriented in the same direction as the view so as to avoid having to rotate the sheet. Reference characters should be so arranged to follow the profile of the object depicted. See 1121 Off. Gaz. Pat. Office 54 (Dec. 25, 1990) and 1129 Off. Gaz. Pat. Office 22 (Aug. 13, 1991).

(q) *Lead lines.* This paragraph is added to integrate international standards, to incorporate brief language which appears in previous § 1.84(f), and to change and expand the definition for lead lines. Lead lines are those lines between the reference characters and the details referred to, and they must be executed in the same way as other lines in the drawing.

(r) *Arrows.* This paragraph is relocated from previous § 1.84(g) and revised to indicate the meaning of the use of arrows, and to show that they may be used at the end of lead lines only if their meaning is clear.

(s) *Copyright or mask work notice.* This paragraph is relocated from previous § 1.84(o).

(t) *Numbering of sheets of drawings.* This paragraph is relocated from previous § 1.84(n) and changed and broadened to allow for the placement of sheet numbers within the sight of the drawing. It is preferable that the sheets be numbered with two Arabic numerals placed on either side of an oblique line, with the first number being the sheet number and the second the total number of sheets of drawings.

(u) *Numbering of views.* This paragraph is relocated from previous § 1.84(i) and, for clarity, is separately identified in this new section. Use of the abbreviation "FIG." must precede all view numbers.

(v) *Security markings.* This paragraph is relocated from previous § 1.84(l) to provide that security markings may be placed on the drawings if they are outside the sight and preferably centered in the top margin.

(w) *Corrections.* This paragraph is added to provide that any corrections made on drawings submitted to the Office must be durable and permanent. The language is revised from previous 1.84(a) which prohibited the use of white pigment to cover lines.

(x) *Holes.* This paragraph is relocated from previous § 1.84(b) to permit two holes to be punched in the top margin of the drawings with their centerlines spaced 7.0 cm. (2¾ inches) apart.

Section 1.88 is removed and reserved since the changes effective January 1, 1991, in § 1.85(b) make the regulation regarding the transfer of drawings unnecessary. Since the Office no longer releases drawings from patent applications, applicants are generally retaining the master copy of the drawings. Accordingly, applicants can easily file a copy of drawings in an application and therefore eliminate the need for the Office to transfer drawings. Any situations which present a hardship to applicants may be accommodated by the filing of a petition under § 1.182 requesting the transfer of the drawings.

Section 1.123 prescribes procedures for amending drawings. With the adoption of new rules for amending drawings effective January 1, 1989, the Office no longer requires the submission of formal drawings upon filing a patent application. See 1097 Off. Gaz. Pat. Office 36 (Dec. 13, 1988). Since corrections are the responsibility of the applicant, the original drawing(s) should be retained by the applicant for future correction, if necessary.

As a result of adoption of the new rules in 1989 relating to drawings, the Office will no longer release to applicants, bonded drafting companies or others, drawings from patent applications. Effective January 1, 1991, § 1.85(b) prohibits release of drawings from all patent applications. Accordingly, the reference to changes by bonded draftsmen is deleted from § 1.123.

Section 1.152 is revised to provide that photographs and ink drawings must not be combined in one design application. The reason for this requirement is to avoid inconsistencies between the photograph and the drawing, and further eliminate views that may distort the proportionate relationship between the corresponding elements on the drawing and the photograph. All design photographs are limited to the design for the article claimed and are not to include environmental structure. Color drawings and color photographs are not permissible in design patent applications. The submission of color photographs will be accepted for filing date purposes, in design patent applications, contrary to the requirement for black ink drawings. The Applications Processing Division has been authorized to construe the color photographs as informal drawings, rather than to hold the applications incomplete as filed. By so construing color photographs when filed as informal drawings, the Office will accept the applications without requiring applicants to file a petition to obtain the original deposit date as the filing date. During the course of prosecution, the Examiner will require properly executed formal black ink drawings or black and white photographs as a substitute for the originally filed color photographs prior to allowance of the claim. Solid black surface shading is not permitted on a design drawing, except when used to represent color contrast.

Section 1.165 is revised to provide that plant patent drawings must comply with the requirements of § 1.84. The current exception that plant patent drawings do not automatically require view numbers and reference characters is maintained. Two sets of the drawings are needed. One set will be forwarded to the Department of Agriculture and the other set will be routed to the Office of Publication and Dissemination, Patent and Trademark Copy Sales, for copying purposes.

Other Considerations

The rule change is in conformity with the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), Executive Orders 12291 and 12612, and the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*

The Acting General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy, Small Business Administration, that these rule changes will not have a significant economic impact on a substantial number of small entities (Regulatory Flexibility Act, 5 U.S.C. 605(b)). The principal impact of these changes is to revise and reformat the drawing standards to adopt international standards, to the extent possible, and to facilitate access to sections through inclusion of pertinent subsection headings, which should be helpful to small entities.

The Office has determined that these rule changes are not a major rule under Executive Order 12291. The annual effect on the economy will be less than $100 million. There will be no major increase in costs or prices for

consumers, individuals, industries, Federal, state or local government agencies, or geographic regions because most of the changes reduce procedural burdens. There will be no adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

The Office has also determined that these rule changes have no Federalism implications affecting the relationship between the National Government and the States as outlined in Executive Order 12612.

These rule changes contain a collection of information requirements subject to the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.*, which has previously been approved by the Office of Management and Budget under Control No. 0651–0011.

List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of information, Inventions and patents, Reporting, and Record keeping requirement.

For the reasons set out in the preamble, and pursuant to the authority contained in 35 U.S.C. 6, Part 1 of Title 37 of the Code of Federal Regulations is amended as set forth below.

PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 6, unless otherwise noted.

2. Section 1.17(h) is revised to read as follows:

§ 1.17 Patent application processing fees.

* * * * *

(h) For filing a petition to the Commissioner under a section of this part listed below which refers to this paragraph.....$130.00

§ 1.47—for filing by other than all the investors or a person not the inventor.

§ 1.48—for correction of inventorship.

§ 1.84—for accepting color drawings or photographs.

§ 1.182—for decision on questions not specifically provided for.

§ 1.183—to suspend the rules.

§ 1.295—for review of refusal to publish a statutory invention registration.

§ 1.377—for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of patent.

§ 1.378(e)—for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in expired patent.

§ 1.644(e)—for petition in an interference.

§ 1.644(f)—for request for reconsideration of a decision on petition in an interference.

§ 1.666(c)—for later filing of interference settlement agreement.

§§ 5.12, 5.13, & 5.14—for expedited handling of a foreign filing license.

§ 5.15—for changing the scope of a license.

§ 5.25—for retroactive license.

* * * * *

3. Section 1.19(a)(3) is revised to read as follows:

§ 1.19 Document supply fees.

* * * * *

(a) Uncertified copies of patents:

* * * * *

(3) Copy of a utility patent or statutory invention registration containing color drawing (see § 1.84(a)(2))..... $24.00

* * * * *

4. Section 1.71(d) is revised to read as follows:

§ 1.71 Detailed description and specification of the invention.

* * * * *

(d) A copyright or mask work notice may be placed in a design or utility patent application adjacent to copyright and mask work material contained therein. The notice may appear at any appropriate portion of the patent application disclosure. For notices in drawings, see § 1.84(s). The content of the notice must be limited to only those elements provided for by law. For example, "©1983 John Doe" (17 U.S.C. 401) and " *M* John Doe" (17 U.S.C. 909) would be properly limited and, under current statutes, legally sufficient notices of copyright and mask work, respectively. Inclusion of a copyright or mask work notice will be permitted only if the authorization language set forth in paragraph (e) of this section is included at the beginning (preferably as the first paragraph) of the specification.

* * * * *

5. Section 1.84 is revised to read as follows:

§ 1.84 Standards for drawings.

(a) *Drawings.* There are two acceptable categories for presenting drawings in utility patent applications:

(1) *Black ink.* Black and white drawings are normally required. India ink, or its equivalent that secures solid black lines, must be used for drawings, or

(2) *Color.* On rare occasions, color drawings may be necessary as the only practical medium by which to disclose the subject matter sought to be patented in a utility patent application or the subject matter of a statutory invention registration. The Patent and Trademark Office will accept color drawings in utility patent applications and statutory invention registrations only after granting a petition filed under this paragraph explaining why the color drawings are necessary. Any such petition must include the following:

(i) The appropriate fee set forth in § 1.17(h);

(ii) Three (3) sets of color drawings; and

(iii) The specification must contain the following language as the first paragraph in that portion of the specification relating to the brief description of the drawing:

"The file of this patent contains at least one drawing executed in color. Copies of this patent with color drawing(s) will be provided by the Patent and Trademark Office upon request and payment of the necessary fee."

If the language is not in the specification, a proposed amendment to insert the language must accompany the petition.

(b) *Photographs.* (1) Black and white. Photographs are not ordinarily permitted in utility and design patent applications. However, the Office will accept photographs in utility and design patent applications only after granting a petition filed under this paragraph which requests that photographs be accepted. Any such petition must include the following:

(i) The appropriate fee set forth in § 1.17(h); and

(ii) Three (3) sets of photographs. Photographs must either be developed on double weight photographic paper or be permanently mounted on bristol board. The photographs must be sufficient quality so that all details in the drawing are reproducible in the printed patent.

(2) Color. Color photographs will be accepted in utility patent applications if the conditions for accepting color drawings have been satisfied. See paragraph (a)(2) of this section.

(c) *Identification of drawings.* Identifying indicia, if provided, should include the application number or the title of the invention, inventor's name, docket number (if any), and the name and telephone number of a person to call if the Office is unable to match the drawings to the proper application. This information should be placed on the back of each sheet of drawings a minimum distance of 1.5 cm. (5/8 inch) down from the top of the page.

(d) *Graphic forms in drawings.* Chemical or mathematical formulae,

tables, and waveforms may be submitted as drawings, and are subject to the same requirements as drawings. Each chemical or mathematical formula must be labeled as a separate figure, using brackets when necessary, to show that information is properly integrated. Each group of waveforms must be presented as a single figure, using a common vertical axis with time extending along the horizontal axis. Each individual waveform discussed in the specification must be identified with a separate letter designation adjacent to the vertical axis.

(e) *Type of paper.* Drawings submitted to the Office must be made on paper which is flexible, strong, white, smooth, non-shiny, and durable. All sheets must be free from cracks, creases, and folds. Only one side of the sheet shall be used for the drawing. Each sheet must be reasonably free from erasures and must be free from alterations, overwritings, and interlineations. Photographs must either be developed on double weight photographic paper or be permanently mounted on bristol board. See paragraph (b) of this section for other requirements for photographs.

(f) *Size of paper.* All drawing sheets in an application must be the same size. One of the shorter sides of the sheet is regarded as its top. The size of the sheets on which drawings are made must be:

(1) 21.6 cm. by 35.6 cm. (8½ by 14 inches),
(2) 21.6 cm. by 33.1 cm. (8½ by 13 inches),
(3) 21.6 cm. by 27.9 cm. (8½ by 11 inches), or
(4) 21.0 cm. by 29.7 cm. (DIN size A4).

(g) *Margins.* The sheets must not contain frames around the sight, i.e., the usable surface. The following margins are required:

(1) On 21.6 cm. by 35.6 cm. (8½ by 14 inch) drawing sheets, each sheet must include a top margin of 5.1 cm. (2 inches), and bottom and side margins of .64 cm. (¼ inch) from the edges, thereby leaving a sight no greater than 20.3 cm. by 29.8 cm. (8 by 11¾ inches).

(2) On 21.6 cm. by 33.1 cm. (8½ by 13 inch) drawing sheets, each sheet must include a top margin of 2.5 cm. (1 inch) and bottom and side margins of .64 cm. (¼ inch) from the edges, thereby leaving a sight no greater than 20.3 cm. by 29.8 cm. (8 by 11¾ inches).

(3) On 21.6 cm. by 27.9 cm. (8½ by 11 inch) drawing sheets, each sheet must include a top margin of 2.5 cm. (1 inch) and bottom and side margins of .64 cm. (¼ inch) from the edges, thereby leaving a sight no greater than 16.9 cm. by 24.3 cm. (6 11/16 by 9 9/16 inches).

(4) On 21.0 cm. by 29.7 cm. (DIN size A4) drawing sheets, each sheet must include a top margin of at least 2.5 cm., a left side margin of 2.5 cm., a right side margin of 1.5 cm., and a bottom margin of 1.0 cm., thereby leaving a sight no greater than 17.0 cm. by 26.2 cm.

(h) *Views.* The drawing must contain as many views as necessary to show the invention. The views may be plan, elevation, section, or perspective views. Detail views of portions of elements, on a larger scale if necessary, may also be used. All views of the drawing must be grouped together and arranged on the sheet(s) without wasting space, preferably in an upright position, clearly separated from one another, and must not be included in the sheets containing the specifications, claims, or abstract. Views must not be connected by projection lines and must not contain center lines. Waveforms of electrical signals may be connected by dashed lines to show the relative timing of the waveforms.

(1) *Exploded views.* Exploded views, with the separated parts embraced by a bracket, to show the relationship or order of assembly of various parts are permissible. When an exploded view is shown in a figure which is on the same sheet as another figure, the exploded view should be placed in brackets.

(2) *Partial views.* When necessary, a view of a large machine or device in its entirety may be broken into partial views on a single sheet, or extended over several sheets if there is no loss in facility of understanding the views. Partial views drawn on separate sheets must always be capable of being linked edge to edge so that no partial view contains parts of another partial view. A smaller scale view should be included showing the whole formed by the partial views and indicating the positions of the parts shown. When a portion of a view is enlarged for magnification purposes, the view and the enlarged view must each be labeled as separate views.

(i) Where views on two or more sheets form, in effect, a single complete view, the views on the several sheets must be so arranged that the complete figure can be assembled without concealing any part of any of the views appearing on the various sheets.

(ii) A very long view may be divided into several parts placed one above the other on a single sheet. However, the relationship between the different parts must be clear and unambiguous.

(3) *Sectional views.* The plane upon which a sectional view is taken should be indicated on the view from which the section is cut by a broken line. The ends of the broken line should be designated by Arabic or Roman numerals corresponding to the view number of the sectional view, and should have arrows to indicate the direction of sight. Hatching must be used to indicate section portions of an object, and must be made by regularly spaced oblique parallel lines spaced sufficiently apart to enable the lines to be distinguished without difficulty. Hatching should not impede the clear reading of the reference characters and lead lines. If it is not possible to place reference characters outside the hatched area, the hatching may be broken off wherever reference characters are inserted. Hatching must be at a substantial angle to the surrounding axes or principal lines, preferably 45°. A cross section must be set out and drawn to show all of the materials as they are shown in the view from which the cross section was taken. The parts in cross section must show proper material(s) by hatching with regularly spaced parallel oblique strokes, the space between strokes being chosen on the basis of the total area to be hatched. The various parts of a cross section of the same item should be hatched in the same manner and should accurately and graphically indicate the nature of the material(s) that is illustrated in cross section. The hatching of juxtaposed different elements must be angled in a different way. In the case of large areas, hatching may be confined to an edging drawn around the entire inside of the outline of the area to be hatched. Different types of hatching should have different conventional meanings as regards the nature of a material seen in cross section.

(4) *Alternate position.* A moved position may be shown by a broken line superimposed upon a suitable view if this can be done without crowding; otherwise, a separate view must be used for this purpose.

(5) *Modified forms.* Modified forms of construction must be shown in separate views.

(i) *Arrangement of views.* One view must not be placed upon another or within the outline of another. All views on the same sheet should stand in the same direction and, if possible, stand so that they can be read with the sheet held in an upright position. If views wider than the width of the sheet are necessary for the clearest illustration of the invention, the sheet may be turned on its side so that the top of the sheet, with the appropriate top margin to be used as the heading space, is on the right-hand side. Words must appear in a horizontal, left-to-right fashion when the page is either upright or turned so that the top becomes the right side, except for graphs utilizing standard scientific convention to denote the axis

of abscissas (of X) and the axis of ordinates (of Y).

(j) *View for Official Gazette.* One of the views should be suitable for publication in the *Official Gazette* as the illustration of the invention.

(k) *Scale.* (1) The scale to which a drawing is made must be large enough to show the mechanism without crowding when the drawing is reduced in size to two-thirds in reproduction. Views of portions of the mechanism on a larger scale should be used when necessary to show details clearly. Two or more sheets may be used if one does not give sufficient room. The number of sheets should be kept to a minimum.

(2) When approved by the examiner, the scale of the drawing may be graphically represented. Indications such as "actual size" or "scale ½" on the drawings, are not permitted, since these lose their meaning with reproduction in a different format.

(3) Elements of the same view must be in proportion to each other, unless a difference in proportion is indispensable for the clarity of the view. Instead of showing elements in different proportion, a supplementary view may be added giving a larger-scale illustration of the element of the initial view. The enlarged element shown in the second view should be surrounded by a finely drawn or "dot-dash" circle in the first view indicating its location without obscuring the view.

(l) *Character of lines, numbers, and letters.* All drawings must be made by a process which will give them satisfactory reproduction characteristics. Every line, number, and letter must be durable, clean, black (except for color drawings), sufficiently dense and dark, and uniformly thick and well-defined. The weight of all lines and letters must be heavy enough to permit adequate reproduction. This requirement applies to all lines however fine, to shading, and to lines representing cut surfaces in sectional views. Lines and strokes of different thicknesses may be used in the same drawing where different thicknesses have a different meaning.

(m) *Shading.* The use of shading in views is encouraged if it aids in understanding the invention and if it does not reduce legibility. Shading is used to indicate the surface or shape of spherical, cylindrical, and conical elements of an object. Flat parts may also be lightly shaded. Such shading is preferred in the case of parts shown in perspective, but not for cross sections. See paragraph (h)(3) of this section. Spaced lines for shading are preferred. These lines must be thin, as few in number as practicable, and they must contrast with the rest of the drawings. As a substitute for shading, heavy lines on the shade side of objects can be used except where they superimpose on each other or obscure reference characters. Light should come from the upper left corner at an angle of 45°. Surface delineations should preferably be shown by proper shading. Solid black shading areas are not permitted, except when used to represent bar graphs or color.

(n) *Symbols.* Graphical drawing symbols may be used for conventional elements when appropriate. The elements for which such symbols and labeled representations are used must be adequately identified in the specification. Known devices should be illustrated by symbols which have a universally recognized conventional meaning and are generally accepted in the art. Other symbols which are not universally recognized may be used, subject to approval by the Office, if they are not likely to be confused with existing conventional symbols, and if they are readily identifiable.

(o) *Legends.* Suitable descriptive legends may be used, or may be required by the Examiner, where necessary for understanding of the drawing, subject to approval by the Office. They should contain as few words as possible.

(p) *Numbers, letters, and reference characters.* (1) Reference characters (numerals are preferred), sheet numbers, and view numbers must be plain and legible, and must not be used in association with brackets or inverted commas, or enclosed within outlines, e.g., encircled. They must be oriented in the same direction as the view so as to avoid having to rotate the sheet. Reference characters should be arranged to follow the profile of the object depicted.

(2) The English alphabet must be used for letters, except where another alphabet is customarily used, such as the Greek alphabet to indicate angles, wavelengths, and mathematical formulas.

(3) Numbers, letters, and reference characters must measure at least .32 cm. (⅛ inch) in height. They should not be placed in the drawing so as to interfere with its comprehension. Therefore, they should not cross or mingle with the lines. They should not be placed upon hatched or shaded surfaces. When necessary, such as indicating a surface or cross section, a reference character may be underlined and a blank space may be left in the hatching or shading where the character occurs so that it appears distinct.

(4) The same part of an invention appearing in more than one view of the drawing must always be designated by the same reference character, and the same reference character must never be used to designate different parts.

(5) Reference characters not mentioned in the description shall not appear in the drawings. Reference characters mentioned in the description must appear in the drawings.

(q) *Lead lines.* Lead lines are those lines between the reference characters and the details referred to. Such lines may be straight or curved and should be as short as possible. They must originate in the immediate proximity of the reference character and extend to the feature indicated. Lead lines must not cross each other. Lead lines are required for each reference character except for those which indicate the surface or cross section on which they are placed. Such a reference character must be underlined to make it clear that a lead line has not been left out by mistake. Lead lines must be executed in the same way as lines in the drawing. See paragraph (1) of this section.

(r) *Arrows.* Arrows may be used at the ends of the lines, provided that their meaning is clear, as follows:

(1) On a lead line, a freestanding arrow to indicate the entire section towards which it points;

(2) On a lead line, an arrow touching a line to indicate the surface shown by the line looking along the direction of the arrow; or

(3) To show the direction of movement.

(s) *Copyright or Mask Work Notice.* A copyright or mask work notice may appear in the drawing, but must be placed within the sight of the drawing immediately below the figure representing the copyright or mask work material and be limited to letters having a print size of .32 cm. to .64 cm. (1/8 to 1/4 inches) high. The content of the notice must be limited to only those elements provided for by law. For example, "©1983 John Doe" (17 U.S.C. 401) and "*M* John Doe" (17 U.S.C. 909) would be properly limited and, under current statutes, legally sufficient notices of copyright and mask work, respectively. Inclusion of a copyright or mask work notice will be permitted only if the authorization language set forth in § 1.71(e) is included at the beginning (preferably as the first paragraph) of the specification.

(t) *Numbering of sheets of drawings.* The sheets of drawings should be numbered in consecutive Arabic numerals, starting with 1, within the sight as defined in paragraph (g) of this section. These numbers, if present, must be placed in the middle of the top of the sheet, but not in the margin. The

numbers can be placed on the right-hand side if the drawing extends too close to the middle of the top edge of the usable surface. The drawing sheet numbering must be clear and larger than the numbers used as reference characters to avoid confusion. The number of each sheet should be shown by two Arabic numerals placed on either side of an oblique line, with the first being the sheet number, and the second being the total number of sheets of drawings, with no other marking.

(u) *Numbering of views.* (1) The different views must be numbered in consecutive Arabic numerals, starting with 1, independent of the numbering of the sheets and, if possible, in the order in which they appear on the drawing sheet(s). Partial views intended to form one complete view, on one or several sheets, must be identified by the same number followed by a capital letter. View numbers must be preceded by the abbreviation "FIG." Where only a single view is used in an application to illustrate the claimed invention, it must not be numbered and the abbreviation "FIG." must not appear.

(2) Numbers and letters identifying the views must be simple and clear and must not be used in association with brackets, circles, or inverted commas. The view numbers must be larger than the numbers used for reference characters.

(v) *Security markings.* Authorized security markings may be placed on the drawings provided they are outside the sight, preferably centered in the top margin.

(w) *Corrections.* Any corrections on drawings submitted to the Office must be durable and permanent.

(x) *Holes.* The drawing sheets may be provided with two holes in the top margin. The holes should be equally spaced from the respective side edges, and their center lines should be spaced 7.0 cm. (2¾ inches) apart. (See § 1.152 for design drawings, § 1.165 for plant drawings, and § 1.174 for reissue drawings.)

§ 1.88 [Removed and Reserved]

6. Section 1.88 is removed and reserved.

7. Section 1.123 is revised to read as follows:

§ 1.123 Amendments to the drawing.

No change in the drawing may be made except with permission of the Office. Permissible changes in the construction shown in any drawing may be made only by the submission of a substitute drawing by applicant. A sketch in permanent ink showing proposed changes, to become part of the record, must be filed for approval by the examiner and should be a separate paper.

8. Section 1.152 is revised to read as follows:

§ 1.152 Design drawing.

The design must be represented by a drawing that complies with the requirements of § 1.84, and must contain a sufficient number of views to constitute a complete disclosure of the appearance of the article. Appropriate surface shading must be used to show the character or contour of the surfaces represented. Solid black surface shading is not permitted except when used to represent color contrast. Broken lines may be used to show visible environmental structure, but may not be used to show hidden planes and surfaces which cannot be seen through opaque materials. Alternate positions of a design component, illustrated by full and broken lines in the same view are not permitted in a design drawing. Photographs and ink drawings must not be combined in one application. Photographs submitted in lieu of ink drawings in design patent applications must comply with § 1.84(b) and must not disclose environmental structure but must be limited to the design for the article claimed. Color drawings and color photographs are not permitted in design patent applications.

9. Section 1.165 is revised to read as follows:

§ 1.165 Plant drawings.

(a) Plant patent drawings should be artistically and competently executed and must comply with the requirements of § 1.84. View numbers and reference characters need not be employed unless required by the examiner. The drawing must disclose all the distinctive characteristics of the plant capable of visual representation.

(b) The drawing may be in color and when color is a distinguishing characteristic of the new variety, the drawing must be in color. Two copies of color drawings or color photographs must be submitted.

Dated: July 14, 1993.

Michael K. Kirk,

Acting Assistant Secretary and Acting Commissioner of Patents and Trademarks.

[FR Doc. 93–17148 Filed 7–19–93; 8:45 am]

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National Oceanic and Atmospheric Administration

50 CFR Part 662

[Docket No. 930769–3169 ID. 061493C]

Northern Anchovy Fishery

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Preliminary determination of harvest quotas; request for comments.

SUMMARY: NMFS announces the estimated spawning biomass and preliminary determination of harvest quotas for the northern anchovy fishery in the exclusive economic zone (EEZ) south of Point Reyes, California, for the 1993–94 fishing season. The harvest quotas have been determined by application of the formulas in the Northern Anchovy Fishery Management Plan (FMP) and its implementing regulations. The optimum yield is set at 4,900 metric tons (mt), which includes a 4,900-mt nonreduction quota, plus an unspecified amount for use as live bait. There is no reduction quota for the 1993–94 fishing season. Final determination of the harvest quotas will be announced shortly after the comment period closes.

DATES: Comments must be received on or before July 29, 1993.

ADDRESSES: Comments should be addressed to Dr. Gary C. Matlock, Acting Regional Director, Southwest Region, National Marine Fisheries Service, 501 W. Ocean Boulevard, suite 4200, Long Beach, CA 90802–4213. Underlying data and other information relevant to this notice (Southwest Fisheries Science Center Administrative Report LJ–93–4), has been compiled in aggregate form and is available for public review during business hours at the office of the NMFS Southwest Regional Director.

FOR FURTHER INFORMATION CONTACT: James J. Morgan, Fisheries Operations, Southwest Region, NMFS, Long Beach, California, (310) 980–4036.

SUPPLEMENTARY INFORMATION: In consultation with the California Department of Fish and Game and the NMFS Southwest Fisheries Science Center, the Acting Director of the Southwest Region, NMFS, (Regional Director) has estimated that the 1993–1994 spawning biomass of the central subpopulation of northern anchovy, *Engraulis mordax*, is 282,000 mt, 136 percent of the 1992–1993 biomass estimate of 208,000 mt. The biomass estimate is derived from a stock synthesis model using spawning biomass estimated by the egg