

Greenville, ME—Greenville Seaplane Base, NDB-A, Amdt. 2.
Mt. Pleasant, IA—Mt. Pleasant Muni. Arpt., NDB Rwy 33, Amdt. 1.
Orr, MN—Orr Public Arpt., NDB Rwy 13, Amdt. 2.
Palestine, TX—Palestine Muni. Arpt., NDB Rwy 35, Amdt. 1.
Palestine, TX—Palestine Muni. Arpt., NDB-A, Original.
Washington, NC—Warren Field, NDB Rwy 35, Original, cancelled.
Washington, NC—Warren Field, NDB-A, Original.

* * * effective December 4, 1975:

Auburn-Lewiston, ME—Auburn-Lewiston Muni. Arpt., NDB Rwy 4, Original.
Auburn-Lewiston, ME—Auburn-Lewiston Muni. Arpt., NDB Rwy 4, Amdt. 6, cancelled.
Burlington, IA—Burlington Muni. Arpt., NDB Rwy 36, Amdt. 2.

4. Section 97.29 is amended by originating, amending, or canceling the following ILS SIAPs, effective January 1, 1976:

Billings, MT—Billings Logan Int'l Arpt., ILS Rwy 9, Amdt. 19.
Fort Worth, TX—Meacham Field, ILS Rwy 16L, Amdt. 2.
New York, NY—John F. Kennedy Int'l Arpt., ILS Rwy 13L, Amdt. 6.
Oklahoma City, OK—Wiley Post Arpt., ILS Rwy 17L, Amdt. 2.

* * * effective December 4, 1975:

Burlington, IA—Burlington Muni. Arpt., ILS Rwy 36, Amdt. 2.
New Orleans, LA—Lakefront Arpt., ILS Rwy 17, Original.

5. Section 97.31 is amended by originating, amending, or canceling the following RADAR SIAPs, effective January 1, 1976:

Billings, MT—Billings Logan Int'l Arpt., RADAR-1, Amdt. 2.
Duluth, MN—Duluth Int'l Arpt., RADAR-1, Amdt. 10.
Grand Rapids, MI—Kent County Arpt., RADAR-1, Amdt. 2.

6. Section 97.33 is amended by originating, amending, or canceling the following RNAV SIAPs, effective January 1, 1976:

Greenwood, MS—Greenwood-LeFlore Arpt., RNAV Rwy 18, Original.
Greenwood, MS—Greenwood-LeFlore Arpt., RNAV Rwy 36, Original.
Sioux City, IA—Sioux City Muni. Arpt., RNAV Rwy 35, Original.

(Secs. 307, 313, 601, 1110, Federal Aviation Act of 1958 (49 U.S.C. 1438, 1354, 1421, 1510); sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)))

Issued in Washington, D.C., on November 13, 1975.

JAMES M. VINES,
Chief,
Aircraft Programs Division.

NOTE: Incorporation by reference provisions in §§ 97.10 and 97.20 (35 FR 5610), approved by the Director of the Federal Register on May 12, 1969.

[FR Doc. 75-31335 Filed 11-19-75; 8:45 am]

Title 21—Food and Drugs CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS: GENERAL

[Docket No. 75N-0293]

PART 201—LABELING

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

Drug Listing Act of 1972; Revision of Implementing Regulations

Correction

In FR Doc. 75-29228 appearing at page 52000 in the issue of Friday, November 7, 1975, on page 52002 in the second complete paragraph in column one insert after the next to the last line "Diagnostic Products, 8757 Georgia Avenue".

SUBCHAPTER D—DRUGS FOR HUMAN USE

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

PART 455—CERTAIN OTHER ANTIBIOTIC DRUGS

Rifampin-Isoniazid Capsules

The Commissioner of Food and Drugs has evaluated data submitted in accordance with regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act, with respect to approval of the antibiotic drug rifampin-isoniazid capsules.

The Commissioner concludes that data supplied by the manufacturer concerning the subject antibiotic drug are adequate to establish its safety and efficacy when used as directed in the labeling and that the regulations should be amended to provide for its certification, effective November 20, 1975.

Therefore, under provisions of the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner (21 CFR 2.120), Parts 431 and 455 are amended to provide for the certification of the antibiotic drug product rifampin-isoniazid capsules:

1. Part 431 is amended in § 431.53 by alphabetically inserting the following item into the table in paragraph (b) (1):

§ 431.51 Fees.	
(b) * * *	
(1) * * *	

		Chargeable fee per test
Test:		
Isoniazid content		27

2. Part 455 is amended by redesignating § 455.170 as § 455.170a and by adding new §§ 455.170 and 455.170b, to read as follows:

§ 455.170 Rifampin oral dosage forms.

§ 455.170a Rifampin capsules.

§ 455.170b Rifampin-isoniazid capsules.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Rifampin-isoniazid capsules contain rifampin and isoniazid with a suitable and harmless filler and with or without binders, lubricants, and stabilizers in a gelatin capsule. Each capsule contains 300 milligrams of rifampin and 150 milligrams of isoniazid. Its rifampin content is satisfactory if it is not less than 90 percent and not more than 130 percent of the number of milligrams of rifampin that it is represented to contain. Its isoniazid content is satisfactory if it is not less than 90 percent and not more than 110 percent of the number of milligrams of isoniazid that it is represented to contain. Its loss on drying is not more than 3.0 percent. The rifampin used conforms to the standards prescribed by § 455.70(a)(1). The isoniazid used conforms to the standards prescribed by the U.S.P.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:
(a) The rifampin used in making the batch for potency, safety, loss on drying, pH, absorptivity, identity, and crystallinity.

(b) The isoniazid used in making the batch for all U.S.P. specifications.

(c) The batch for rifampin content, isoniazid content, and loss on drying.

(ii) *Samples required:*

(a) The rifampin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(b) The batch: A minimum of 36 capsules.

(b) *Tests and methods of assay*—(1) *Rifampin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place a representative number of capsules into a high-speed glass blender jar containing 200 milliliters of methyl alcohol and blend for 3 minutes. Add 300 milliliters of 1 percent potassium phosphate buffer, pH 6.0 (solution 1), and blend for 3 to 5 minutes. Remove an aliquot and further dilute with solution 1 to the reference concentration of 5.0 micrograms of rifampin per milliliter (estimated).

(2) *Isoniazid content*—(i) *Equipment*—(a) *Electronic voltmeter.* A vacuum tube voltmeter or pH meter capable of measuring potentials from 0 to 1,400 millivolts.

(b) *Platinum electrodes.* Use twin platinum electrodes.

(c) *Constant current potential source.* Polarize the platinum electrodes by

means of a battery and a suitable resistance in series with the electrodes, or by a stable electronic power supply, so that the current flow is about 2.5 microamperes.

(d) *Titration vessel.* Use a 100-milliliter beaker.

(ii) *Reagents*—(a) Concentrated hydrochloric acid, reagent grade.

(b) 0.1N Bromine solution. Dissolve 3.0 grams of potassium bromate and 15.0 grams of potassium bromide in sufficient water to make 1 liter. Preserve in dark amber-colored, glass-stoppered bottles.

(c) 1.0N Potassium iodide. Dissolve 16.5 grams of potassium iodide in 100 milliliters of water.

(d) Starch iodide paste, T.S. (U.S.P.).

(e) 0.1N Sodium thiosulfate (U.S.P.).

(f) 0.1N Hydrochloric acid.

(g) Chloroform, reagent grade.

(iii) *Standardization of 0.1N bromine solution.* Measure accurately about 25 milliliters of the bromine solution into a 500-milliliter iodine flask and dilute with 120 milliliters of water. Add 5 milliliters of hydrochloric acid, insert the stopper in the flask, and shake it gently. Then add 5 milliliters of potassium iodide T.S., insert the stopper, shake the mixture, and allow it to stand for 5 minutes. Titrate the liberated iodine with standard 0.1N sodium thiosulfate U.S.P., adding starch iodide paste T.S./U.S.P. as the endpoint

is approached. Calculate the normality of the bromine solution.

(iv) *Preparation of sample solution.* Empty the contents of not less than 10 capsules into a tared weighing bottle. Mix and weigh the powder. Calculate the average capsule weight content and accurately weigh a sample equivalent to approximately 100 milligrams of isoniazid. Transfer the sample to a 125-milliliter separatory funnel. Add 20 milliliters of 0.1N hydrochloric acid and shake well. Extract the acidic solution with six 25-milliliter portions of chloroform, combining any interfacial emulsion with the aqueous phase throughout the extraction procedure. Discard the chloroform extracts. Quantitatively transfer the acidic aqueous layer to a 100-milliliter volumetric flask and dilute to volume with 0.1N hydrochloric acid.

(v) *Titration procedure.* Pipet 25 milliliters of the sample solution into the titration vessel and add 10 milliliters of concentrated hydrochloric acid. Adjust the volume to approximately 50 milliliters with water. Titrate potentiometrically at constant current with 0.1N bromine solution to a dead stop endpoint. Calculate the isoniazid content for the sample used and determine the isoniazid content for the average capsule weight as follows:

$$\text{Milligrams Isoniazid per average capsule} = \frac{V \times N \times 34.29 \times 4 \times W}{S}$$

where:

V = Volume in milliliters of 0.1N bromine solution used to titrate the sample;

N = Normality of bromine solution;

W = Average capsule weight content in milligrams;

S = Weight of sample in milligrams.

(3) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

Since the conditions prerequisite for providing for the certification of the subject antibiotic have been complied with, and since the matter is noncontroversial, notice and public procedures and delayed effective date are not prerequisites to this promulgation.

Effective date. This amendment shall be effective November 20, 1975.

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357))

Dated: November 14, 1975.

MARY A. McENTYRE,
Assistant to the Director for
Regulatory Affairs, Bureau of
Drugs.

[FR Doc.75-31364 Filed 11-19-75;8:45 am]

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

Sterile Bleomycin Sulfate Correction

In FR Doc. 75-29849 appearing at page 52003 in the issue of Friday, November 7, 1975, on page 52005 in the sixth line of § 450.10a(a)(1)(ix) in column one "bleomycin B₂" should read "bleomycin B₁".

Issued in Washington, D.C., this 14th day of November 1975.

JAMES D. HUTCHINSON,
Administrator for Pension,
and Welfare Benefit Programs.

[FR Doc.75-31316 Filed 11-19-75;8:45 am]

PART 2556—INTERPRETIVE BULLETINS RELATING TO REPORTING AND DISCLOSURE

Independence of Accountant Retained by Employee Benefit Plan

For Immediate Release: November 19, 1975 ERISA IB RD 75-1.

The Department of Labor today announced guidelines for determining when a qualified public accountant is independent for purposes of auditing and rendering an opinion on the financial information required to be included in the annual report filed with the Department.

Section 103(a)(3)(A) requires that the accountant retained by an employee benefit plan be "independent" for purposes of examining plan financial information and rendering an opinion on the financial statements and schedules required to be contained in the annual report.

Under the authority of section 103(a)(3)(A) the Department of Labor will not recognize any person as an independent qualified public accountant who is in fact not independent with respect to the employee benefit plan upon which that accountant renders an opinion in the annual report filed with the Department of Labor. For example, an accountant will not be considered independent with respect to a plan if:

(1) During the period of professional engagement to examine the financial statements being reported, at the date of the opinion, or during the period covered by the financial statements, the accountant or his or her firm or a member thereof had, or was committed to acquire, any direct financial interest or any material indirect financial interest in such plan, or the plan sponsor, as that term is defined in section 3(16)(B) of the Act.

(2) During the period of professional engagement to examine the financial statements being reported, at the date of the opinion, or during the period covered by the financial statements, the accountant, his or her firm or a member thereof was connected as a promoter, underwriter, investment advisor, voting trustee, director, officer, or employee of the plan or plan sponsor except that a firm will not be deemed not independent in regard to a particular plan if a former officer or employee of such plan or plan sponsor is employed by the firm and such individual has completely disassociated himself from the plan or plan sponsor and does not participate in auditing financial statements of the plan covering any period of his or her employment by the plan or plan sponsor. For the purpose of this bulletin the term "member" means all partners or shareholder employees in the firm and all professional employees participating in the audit or

Title 29—Labor

CHAPTER XXV—OFFICE OF EMPLOYEE BENEFITS SECURITY, DEPARTMENT OF LABOR

PART 2556—INTERPRETIVE BULLETINS RELATING TO REPORTING AND DISCLOSURE

Employee Retirement Income Security Act of 1974

In order to provide a concise and ready reference to its interpretations of the provisions of Part I of Title I of the Employee Retirement Income Security Act of 1974, relating to reporting and disclosure, the Department of Labor will hereafter publish its interpretive bulletins pertaining to reporting and disclosure in the rules and regulations section of the FEDERAL REGISTER.

Copies of the various interpretive bulletins may be obtained from the Labor Management Services Administration Information Office, Room N-5641, New Department of Labor Building, 200 Constitution Avenue, N.W., Washington, D.C., 20210.

Accordingly, 29 CFR Chapter XXV is amended by adding a new Part 2556, Interpretive Bulletins Relating to Reporting and Disclosure.

located in an office of the firm participating in a significant portion of the audit;

(3) An accountant or a member or an accounting firm maintains financial records for the employee benefit plan.

However, an independent qualified public accountant may permissibly engage in or have members of his or her firm engage in certain activities which will not have the effect of removing recognition of his or her independence. For example, (1) an accountant will not fail to be recognized as independent if at or during the period of his or her professional engagement with the employee benefit plan the accountant or his or her firm is retained or engaged on a professional basis by the plan sponsor, as that term is defined in section 3(16)(B) of the Act. However, to retain recognition of independence under such circumstances the accountant must not violate the prohibitions against recognition of independence established under paragraphs (1), (2) or (3) of this interpretive bulletin; (2) the rendering of services by an actuary associated with an accountant or accounting firm's independence. However, it should be noted that the rendering of services to a plan by an actuary and accountant employed by the same firm may constitute a prohibited transaction under section 406(a)(1)(C) of the Act. The rendering of such multiple services to a plan by a firm will be the subject of a later interpretive bulletin that will be issued by the Department of Labor.

In determining whether an accountant or accounting firm is not, in fact, independent with respect to a particular plan, the Department of Labor will give appropriate consideration to all relevant circumstances, including evidence bearing on all relationships between the accountant or accounting firm and that of the plan sponsor or any affiliate thereof, and will not confine itself to the relationships existing in connection with the filing of annual reports with the Department of Labor.

Further interpretive bulletins may be issued by the Department of Labor concerning the question of independence of an accountant retained by an employee benefit plan.

Issued in Washington, D.C., this 14th day of November 1975.

JAMES D. HUTCHINSON,
Administrator for Pension
and Welfare Benefit Programs.

[FR Doc.75-31318 Filed 11-19-75; 8:45 am]

Title 32—National Defense

CHAPTER XII—DEFENSE SUPPLY AGENCY

SUBCHAPTER B—MISCELLANEOUS

PART 1285—AVAILABILITY TO THE PUBLIC OF OFFICIAL INFORMATION

Appendix A—Schedules of Fees; Correction

In FR Doc. 75-4501, Volume 40—Number 34, published at page 7282 in the issue dated Wednesday, February 19, 1975, is corrected by changing fees under

"Search" from "\$6.50, 3.50, 13.00, 10.00" to "\$5.50, 2.75, 11.00, 5.50" and under "Computer Service Charges," line 4, by changing "if" to "of".

J. J. McALEER, Jr.,
Colonel, USA,
Staff Director, Administration.

[FR Doc.75-31354 Filed 11-19-75; 8:45 am]

Title 40—Protection of Environment CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

[FRL 456-7]

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

New Hampshire Plan; Revision

On May 31, 1972 (37 FR 10842), pursuant to section 110 of the Clean Air Act and 40 CFR Part 51, the Administrator approved, with exceptions, the New Hampshire Plan for attainment of national ambient air quality standards. Included in this approval were Regulations 4, 6, 8, 10, 11, 13, 14, and 17. This publication contains the Administrator's approval of a revision to these regulations.

New Hampshire has revised the following regulations and submitted them to EPA for approval as a revision to the New Hampshire State Implementation Plan: Regulation 4, Control of Visible and Particulate Emissions from Fuel Burning Equipment; Regulation 6, Prevention, Abatement and Control of Air Contaminants from Incinerators; Regulation 8, Emissions from Asphalt Plants; Regulation 10, Prevention, Abatement and Control of Air Contaminants from Ferrous Foundries; Regulation 11, Ambient Air Quality Standards for the State of New Hampshire; Regulation 13, Prevention, Abatement and Control of Air Contaminants from the Sand and Gravel Industry and the Cement, Ready Mix Concrete and Cement Block Industry; Regulation 14, Prevention, Abatement and Control of Air Contaminants from Non-Ferrous Foundries, Smelters, and Investment Casting Industries; Regulation 17, Prevention, Abatement and Control of Air Contaminants from Process, Manufacturing, Service and Miscellaneous Industries.

The revision in Regulation No. 4 exempts new steam generators over 250 million BTU/hr heat input from the visible emission control limitation, allowing up to a 40 percent opacity reading for two minutes in any one hour.

Regulation No. 6 has added a definition for "Heating Values".

Regulation No. 8 has added a requirement for the submission of data on type, sizing and quantity of aggregates used and hours of plant operation for new or modified asphalt plants.

Regulation No. 10 has been revised to prohibit new or modified ferrous foundries from discharging into the atmosphere any gases which contain particulate matter in excess of 50 milligrams per dry standard m³ (0.022 grains dsfc).

Regulation 11 adds the following primary ambient air quality standard for sulfur dioxide: Maximum three hour average 1300 µg/m³, 0.5 ppm not to be exceeded more than once per year.

Regulation 13 adds a definition of Portland Cement Plants.

Regulation 14 adds a definition of opacity.

Regulation 17 adds testing definitions for: Nitric Acid Production Unit, Sulfuric Acid Production Unit, and for opacity.

As proposed, the changes to regulations 4, 6, 8, 10, 11, 13, 14 and 17 bring existing regulations into conformity with Federal New Source Performance Standards promulgated December 23, 1971, and March 8, 1974. The change in Regulation 11 will insure conformance with the Federal ambient air quality standards for sulfur dioxide (SO₂).

The proposed revision was published as proposed rulemaking on August 21, 1974 (39 FR 30167) and opportunity was provided for the public to comment on the approvability of the revision. The comment period has expired with no comments being received.

After evaluation of the State's submittal, the Administrator has determined that the regulation, as amended, meets the requirements of the Clean Air Act and 40 CFR Part 51. This regulation is hereby approved as a revision to the New Hampshire Implementation Plan.

The Agency finds that good cause exists for making these actions effective immediately on November 20, 1975, for the following reasons:

1. The implementation plan revisions were adopted in accordance with procedural requirements of State and Federal law, which provided for adequate public hearings and comments, and further participation is unnecessary and impracticable.

2. Immediate effectiveness of the actions enables the sources involved to proceed with certainty in conducting their affairs, and persons wishing to seek judicial review of the actions may do so without delay.

This revision becomes effective on November 20, 1975.

(Sec. 110, Clean Air Act, as amended, (42 U.S.C. 1857c-5))

Dated: November 13, 1975.

JOHN QUARLES,
Acting Administrator.

Part 52 of Chapter I, Title 40, Code of Federal Regulations, is amended as follows:

Subpart EE—New Hampshire

§ 52.1520 [Amended]

Section 52.1520(d) is amended by inserting the date "June 6, 1974" in proper chronological order.

[FR Doc.75-31313 Filed 11-19-75; 8:45 am]