Effective date. This amendment shall become effective January 22, 1974.

LEO G. K. IVERSON,
Deputy Administrator, Plant Protection and Quarantine Programs.

[FR Doc.74-1794 Filed 1-21-74;8:45 am]

[No. 74-16]

Title 12—Banks and Banking

CHAPTER V—FEDERAL HOME LOAN BANK BOARD

SUBCHAPTER D—FEDERAL SAVINGS AND LOAN INSURANCE CORPORATION

PART 563—OPERATIONS

Premiums, Benefits, and Charges; Correction

JANUARY 16, 1974.

The Federal Home Loan Bank Board hereby corrects FR Doc. No. 74-1011 amending § 563.23-1 of the Rules and Regulations for Insurance of Accounts (12 CFR 563.23-1) which was published in the issue dated January 14, 1974, at 39 FR 1745, by deleting the word "fee" as it appears in the penultimate paragraph of the preamble to the regulation following the phrase "one percent of the original loan commitment * * *."

By the Federal Home Loan Bank Board.

[SEAL] EUGENE M. HERRIN,
Assistant Secretary.

[FR Doc.74-1746 Filed 1-21-74;8:45 am]

Title 14—Aeronautics and Space

CHAPTER I—FEDERAL AVIATION ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

[Docket No. 72-CE-34-AD; Amdt. 39-1771]

PART 39—AIRWORTHINESS DIRECTIVES

Beech Models 50, 65, 65-80 and 70 Series Airplanes

AD 73-23-4, Amendment 39-1740 (38 FR 30867) applicable to Beech Models 50, 65, 65-80 and 70 series airplanes is an airworthiness Directive (AD) which requires the installation of either Beech Nacelle Interior Fire Seal Kits Nos. 65-9008-1 or 65-9008-3, as applicable, within 100 hours' time in service after January 1, 1974.

Subsequent to the issuance of AD 73-23-4 the manufacturer has advised that the subject kits will not be available for modifying the airplanes in accordance with the present compliance time provided in this AD. The Federal Aviation Administration has reviewed the service records on these airplanes and finds that the extension of compliance time for AD 73-23-4 will not materially reduce the level of safety in operating the affected aircraft. Accordingly, a new compliance time of 100 hours' time in service after April 1, 1974, for AD 73-23-4 is being established.

Since this amendment is relaxatory in nature and imposes no additional burden on any person, compliance with the notice and public procedure provisions of the Administrative Procedure Act is not necessary and good cause exists for making this amendment effective in less than thirty (30) days.

In consideration of the foregoing and pursuant to the authority delegated to me by the Administrator 14 CFR 11.89 (31 FR 13697), § 39.13 of Part 39 of the Federal Aviation Regulations, Amendment 39-1740 (38 FR 30867), AD 73-23-4, is amended as follows:

The compliance paragraph is amended so that it now reads as follows:

Compliance: Required within the next 100 hours' time in service after April 1, 1974, unless already accomplished.

This amendment becomes effective January 24, 1974.

(Sec. 313(a), 601, 603, Federal Aviation Act of 1958 (49 U.S.C. 1354(a), 1421 and 1423); sec. 6(c) of the Department of Transportation Act (49 U.S.C. 1655(c)))

Issued in Kansas City, Missouri, on January 10, 1974.

A. L. COULTER,
Director, Central Region.

[FR Doc.74-1726 Filed 1-21-74;8:45 am]

Title 18—Conservation of Power and Water Resources

CHAPTER I—FEDERAL POWER COMMISSION

[Docket No. R-412; Order 473]

UNIFORM SYSTEM OF ACCOUNTS

Accounting for Gains and Losses of Utility Property That Had Been Classified in Utility Service; Certain Depreciation and Amortization Accounts; Correction

DECEMBER 27, 1973.

The following corrections are made to FR Doc. 73-3444, issued February 15, 1973, and published at 38 FR 4947, on February 23, 1973:

PART 101—UNIFORM SYSTEM OF ACCOUNTS PRESCRIBED FOR CLASS A AND CLASS B PUBLIC UTILITIES AND LICENSES

Preceding ordering paragraph A.3. (page 4949) add new ordering paragraph A.3. and recodify present ordering paragraph as A.4. to read as follows:

3. Amend paragraph C of the text of "Account 302, Franchises and Consents" of the Electric Plant Accounts. As amended, account 302 reads:

Electric Plant Accounts

1. INTANGIBLE PLANT

* * * * *

302 Franchises and consents.

* * * * *

C. When any franchise has expired, the book cost thereof shall be credited hereto and charged to account 426.5, Other Deductions, or to account 111, Accumulated Provision for Amortization of Electric Utility Plant, as appropriate.

* * * * *

4. (Previously codified 3)

* * * * *

PART 104—UNIFORM SYSTEM OF ACCOUNTS FOR CLASS C AND CLASS D PUBLIC UTILITIES AND LICENSEES

Preceding ordering paragraph B.3. (page 4949) add new ordering paragraph B.3. and recodify present ordering paragraph as B.4. to read as follows:

3. Amend paragraph C of the text of "Account 302, Franchises and Consents" of the Electric Plant Accounts. As amended, account 302 reads:

Electric Plant Accounts

1. INTANGIBLE PLANT

* * * * *

302 Franchises and consents.

* * * * *

C. When any franchise has expired, the book cost thereof shall be credited hereto and charged to account 426.5, Other Deductions, or to account 110, Accumulated Provision for Depreciation and Amortization of Electric Utility Plant, as appropriate.

* * * * *

4. (Previously codified 3)

* * * * *

PART 201—UNIFORM SYSTEM OF ACCOUNTS FOR NATURAL GAS COMPANIES

Preceding ordering paragraph D.1. (page 4950) add new ordering paragraph D.1. and recodify present ordering paragraph D.1. as D.2. to read as follows:

1. Amend the list of accounts under General Instruction 16. *Significance of Commission Opinion Nos. 568 and 568A on Accounting*. As amended, General Instruction 16 reads:

General Instructions

* * * * *

16. Significance of Commission Opinion Nos. 568 and 568A on Accounting.

* * * * *

111 Accumulated Provision for Amortization and Depletion of Gas Utility Plant.

* * * * *

2. (Previously codified 1)

* * * * *

Recodify ordering paragraph D.2. and D.3. (page 4950) as D.3. and D.4. to read as follows:

3. (Previously codified 2)

* * * * *

4. (Previously codified 3)

* * * * *

Preceding ordering paragraph D.4. (page 4951) add new ordering paragraph D.5. and recodify present ordering paragraph D.4. as D.6. to read as follows:

5. Amend paragraph C of the text of "Account 302, Franchises and Consents" of the Gas Plant Accounts. As amended account 302 reads:

Gas Plant Accounts

1. INTANGIBLE PLANT

* * * * *

302 Franchises and consents.

* * * * *

C. When any franchise has expired, the book cost thereof shall be credited hereto and charged to account 426.5, Other Deductions, or to account 111, Accumulated Provision for Amortization and Depletion of Gas Utility Plant, as appropriate.

* * * * *

6. (Previously codified 4)

* * * * *

Recodify ordering paragraph D.5. (page 4951) as D.7. and amend the text of Account 797, Abandoned Leases, of the Operation and Maintenance Expense Accounts, in accordance with Docket No. R-403, Order No. 440-A, issued January 5, 1973, to read as follows:

* * * * *

Operation and Maintenance Expense Accounts

* * * * *

1. PRODUCTION EXPENSES

* * * * *

C. EXPLORATION AND DEVELOPMENT EXPENSES

* * * * *

797 Abandoned leases.

A. This account shall be charged with amounts credited to account 111, Accumulated Provision for Amortization and Depletion of Gas Utility Plant, to cover the probable loss on abandonment of natural gas leases acquired before October 8, 1969, included in account 105, Gas Plant Held for Future Use, which has never been productive.

B. When natural gas leaseholds which were acquired before October 8, 1969, and which have never been productive are abandoned, and the amounts provided in account 111, Accumulated Provision for Amortization and Depletion of Gas Utility Plant, are not sufficient to cover the cost thereof, the deficiency shall be charged to this account unless otherwise authorized or directed by the Commission. (See account 182.)

* * * * *

PART 204—UNIFORM SYSTEM OF ACCOUNTS FOR CLASS C AND CLASS D NATURAL GAS COMPANIES

Preceding ordering paragraph E.3. add new ordering paragraph E.3. and recodify present ordering paragraph E.3. as E.4. to read as follows:

3. Amend paragraph C of the text of "Account 302, Franchises and Consents" of the Gas Plant Accounts. As amended account 302 reads:

Gas Plant Accounts

1. INTANGIBLE PLANT

* * * * *

302 Franchises and consents.

* * * * *

C. When any franchise has expired, the book cost thereof shall be credited hereto and charged to account 426.5, Other Deductions, or to account 110, Accumulated Provision for Depreciation, Depletion and Amortization of Gas Utility Plant, as appropriate.

* * * * *

4. (Previously codified 3)

* * * * *

KENNETH F. PLUMB,
Secretary.

[FR Doc.74-1798 Filed 1-21-74;8:45 am]

Title 19—Customs Duties

CHAPTER I—UNITED STATES CUSTOMS SERVICE, DEPARTMENT OF THE TREASURY

[T.D. 74-38]

PART 134—COUNTRY OF ORIGIN MARKING

Country of Origin Marking

Marking of Imported Eyeglass and Sunglass Frames

Pursuant to section 304(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1304(a)), and section 134.42 of the Customs Regulations (19 CFR 134.42), relating to the marking of imported merchandise as to its country of origin, notice is hereby given that imported eyeglass and sunglass frames, whether assembled or unassembled, must be so marked by means of die stamping in a contrasting color, by raised lettering, by engraving, or by some other method producing a permanent mark. The marking must be legible and conspicuous and must clearly indicate the country of origin to the ultimate purchaser in the United States by the words "Frame made in (country of origin)" or "Frame—(country of origin)".

Imported eyeglass or sunglass frames marked by means of ink stamping, tagging with adhesive labels, or any other impermanent form of marking which permits the mark to be smudged, blurred, or otherwise easily obliterated or removed are not considered to be acceptably marked as to country of origin for purposes of section 304 of the Tariff Act of 1930, as amended (19 U.S.C. 1304), and Part 134 of the Customs Regulations (19 CFR Part 134).

Effective date. The above ruling shall be effective as to merchandise entered, or withdrawn from warehouse, for consumption on or after April 22, 1974.

[SEAL] VERNON D. ACREE,
Commissioner of Customs.

[FR Doc.74-1767 Filed 1-21-74;8:45 am]

[T.D. 74-41]

PART 151—EXAMINATION, SAMPLING, AND TESTING OF MERCHANDISE

Brix Values

On September 13, 1973, there was published in the FEDERAL REGISTER (38 FR 25448) a notice of proposed rulemaking, finding the average Brix value for Bilberry (Whortleberry, *Vaccinium Myrtillum*) juice to be 13.4 degrees and for Soursop (Guanabana, *Annono Muricata*) juice to be 16.0 degrees, and amending § 151.91 of the Customs Regulations to add this information to the list of the average Brix values for unconcentrated natural fruit juices set forth therein. No comments were received in response to this notice of proposed rulemaking.

Accordingly, the alphabetical listing of unconcentrated natural fruit juices whose Brix values have been determined, as set forth in § 151.91 of the Customs Regulations, is amended by inserting "Bilberry (Whortleberry, *Vaccinium Myrtillum*)—13.4" after "Apricot—14.3" and before "Black currant—15.0", and by inserting "Soursop (Guanabana, *Annono Muricata*)—16.0" after "Red currant—10.5" and before "Strawberry—8.0".

(R.S. 251, as amended, sec. 624, 46 Stat. 759, 77A Stat. 14, 63; 19 U.S.C. 66, 1202 (Gen. Hdnte. 12, sch. 1, pt. 12A hdnte. 3(b)), 1624)

Effective date. This amendment shall become effective on February 21, 1974.

[SEAL] VERNON D. ACREE,
Commissioner of Customs.

Approved: January 14, 1974.

EDWARD L. MORGAN,
Assistant Secretary of the Treasury.

[FR Doc.74-1788 Filed 1-21-74;8:45 am]

[T.D. 74-37]

PART 174—PROTESTS

Time for Review

On August 13, 1973, there was published in the FEDERAL REGISTER (38 FR 21785), a notice of a proposed amendment to section 174.21 of the Customs Regulations (19 CFR 174.21), to provide for the prompt disposition of protests concerning merchandise excluded from entry or delivery under any provision of the Customs laws. The proposed amendment directs the district directors of Customs to review and act on such protests within 30 days from the date they are filed unless the person seeking entry or delivery of the merchandise requests additional time for the submission of evidence or arguments. However, notwithstanding the 30-day period allowed the district directors, they will process such protests as expeditiously as possible.

After careful consideration of the comments received in response to the notice of the proposed amendment, no changes in the proposed amendment were deemed necessary.

Accordingly, § 174.21 of the Customs Regulations is amended to read as follows:

§ 174.21 Time for review of protests.

(a) *In general.* Except as provided in paragraph (b) of this section, the district director shall review and act on a protest filed in accordance with section 514, Tariff Act of 1930, as amended (19 U.S.C. 1514), within 2 years from the date the protest was filed. If several timely filed protests are treated as part of a single protest pursuant to section 174.15, the 2-year period shall be deemed to run from the date the last such protest was filed in accordance with section

514, Tariff Act of 1930, as amended (19 U.S.C. 1514).

(b) *Protests relating to exclusion of merchandise.* If the protest relates to an administrative action involving exclusion of merchandise from entry or delivery under any provision of the Customs laws, the district director shall review and act on a protest filed in accordance with section 514, Tariff Act of 1930, as amended (19 U.S.C. 1514), within 30 days from the date the protest was filed, unless the person filing the protest shall request an additional delay for the purpose of presenting evidence or argument with respect to the matters involved in the protest. In no event shall the district director (or the Commissioner of Customs or his designee if the protest is the subject of further review as provided for in §§ 174.25 and 174.26) delay action on the protest beyond 30 days, or such additional time period as may be agreed to by the person filing the protest. Any protest filed pursuant to this paragraph shall clearly so state on its face.

(R.S. 251, as amended, secs. 515, 624, 46 Stat. 736, as amended, 759; 19 U.S.C. 66, 1515, 1624)

Effective date. This amendment shall become effective on February 21, 1974.

[SEAL] VERNON D. ACREE,
Commissioner of Customs.

Approved: January 10, 1974.

JAMES B. CLAWSON,
Acting Assistant Secretary of the Treasury.

[FR Doc.74-1766 Filed 1-21-74;8:45 am]

[T.D. 74-42]

PART 134—COUNTRY OF ORIGIN MARKING

"Danmark" an Acceptable Variant Spelling of "Denmark"

JANUARY 16, 1974.

Pursuant to section 134.45(a) of the Customs Regulations (19 CFR 134.45-(a)), notice is hereby given that the word "Danmark" is an acceptable variant spelling of "Denmark" for country of origin marking purposes.

Merchandise made in Denmark has recently been imported into the United States marked with the word "Danmark" to indicate the country of origin. Section 134.45(b) of the Customs Regulations provides that markings in the form of variant spellings of the English name of the country of origin which clearly indicate its name, such as "Brasil" for "Brazil" and "Italie" for "Italy," are acceptable. "Danmark" is an acceptable variant spelling of the English "Denmark" inasmuch as it clearly indicates that country's name for country of origin marking purposes.

[SEAL] VERNON D. ACREE,
Commissioner of Customs.

[FR Doc.74-1791 Filed 1-21-74;8:45 am]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

Conditions for Marketing of Digoxin Products

In April, 1970, the Food and Drug Administration inaugurated a program to systematically test marketed batches of digoxin tablets after the agency became aware of an apparent potency problem with this cardiac glycoside. As a result of this testing program, from April to November, 1970, there were 79 recalls of digoxin products. In October, 1970, a voluntary certification program was initiated whereby participating manufacturers agreed not to release new batches of digoxin tablets until samples of the batches were tested by the Food and Drug Administration and found to meet The United States Pharmacopeia (USP) requirements for potency and content uniformity.

In December, 1971, John Lindenbaum, M.D. and his colleagues published a paper in The New England Journal of Medicine (Lindenbaum, J., Mellow, M. G., Blackstone, M. D., Butler, V. P., "Variation in Biologic Availability of Digoxin from Four Preparations", The New England Journal of Medicine, 285:1344, 1971) describing a study of the biologic availability in normal human volunteers of 4 batches of commercially marketed digoxin tablets. The study noted marked differences in serum digoxin levels achieved with tablets produced by different manufacturers. Significant variation between different batches prepared by a single manufacturer was also observed. Lindenbaum conducted the study after observing low serum digoxin concentrations in several patients receiving unusually large maintenance doses of digoxin.

The tablets used in the study had not been analyzed for compliance with compendial specifications including potency and content uniformity. Subsequently, the Food and Drug Administration analyzed tablets from batches used in the Lindenbaum study and found that the two batches which gave acceptable serum digoxin levels met these compendial specifications. One batch which had given very low serum digoxin levels did not meet these compendial specifications varying from 76 to 152 percent of labeled potency. At that time sufficient tablets of the other batch which gave low serum digoxin levels could not be found for analysis. On this basis, it was the Food and Drug Administration's view that the problem identified by Lindenbaum may have been one of potency and not bioavailability (Vitti, T. G., Banes, D., Byers, T. E., "Bioavailability of Digoxin", The New England Journal of Medicine, 285:1433, 1971).

Somewhat prior to this, the Food and Drug Administration had begun a systematic investigation of several formulations of the cardiac glycosides. John G. Wagner, Ph.D., Professor of Pharmacy, Upjohn Center for Clinical Pharmacology, University of Michigan, Ann Arbor, Michigan, under an extramural contract with the Food and Drug Administration, had just completed a pharmacokinetic evaluation of digitoxin when the agency learned of the results of the Lindenbaum study. Dr. Wagner then proceeded to study the bioequivalence of digoxin tablets. In addition to conducting a bioavailability study on digoxin tablets made by two different manufacturers, Dr. Wagner developed a reproducible in vitro dissolution test which showed significant correlation with in vivo bioavailability test results. The results of the Wagner study were published in The Journal of the American Medical Association in April, 1973 (Wagner, J. G., et al., "Equivalence Lack in Digoxin Plasma Levels," Journal of the American Medical Association, 224:199-204, 1973).

In the meantime, sufficient tablets of the second batch of digoxin tablets which gave low serum digoxin levels in the Lindenbaum study were located for chemical analysis. The Food and Drug Administration's analysis showed that the tablets met the compendial specifications for content uniformity. It was therefore apparent that the problem identified originally by Lindenbaum and his colleagues was attributable to bioavailability and not to potency (Skelly, J. and Knapp, G., "Biologic Availability of Digoxin Tablets," Journal of the American Medical Association, 224:243, 1973).

The Food and Drug Administration recognized that very few well controlled digoxin bioavailability studies had been performed and was aware of data which indicated that even the possibility of batch-to-batch bioavailability inconsistency could not be discounted. The agency continued to implement studies to determine the dimension of the problem and to provide the basis for a systematic regulatory approach to assure the uniformity of all digoxin products. In addition to inaugurating additional in vivo studies under the extramural contract program, the agency, in its own laboratories, adapted, modified, and validated several dissolution procedures in both acid and water media based on the method originally developed by Dr. Wagner. Samples of digoxin tablets produced by all known manufacturers were obtained for laboratory analysis. A dissolution profile was obtained on all the tablets which met compendial requirements for potency and content uniformity. A satisfactory correlation existed with the available in vivo data.

The USP in conjunction with the FDA have initiated studies to determine the correlation between bioavailability in vivo and the dissolution rate of digoxin tablets in vitro. As a result of the avail-