generally good on larger sizes and weaker on smaller sizes.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the **Federal Register** (5 U.S.C 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared purposes of the Act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the Act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

List of Subjects in 7 CFR Part 910

Marketing agreements and orders, California, Arizona, Lemons.

Section 910.725 is added as follows:

§ 910.725 Lemon regulation 425.

The quantity of lemons grown in California and Arizona which may be handled during the period August 21, 1983, through August 27, 1983, is established at 246,200 cartons.

(Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674)

Dated: August 18, 1983.

Charles R. Brader,

Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 83-23054 Filed 8-18-83; 11:55 am]

BILLING CODE 3410-02-M

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

8 CFR Parts 212 and 235

Documentary Requirements; Nonimmigrants; Waivers; Admission of Certain Inadmissible Aliens; Parole; Inspection of Persons Applying for Admission; Revised Processing Procedures

Correction

In FR Doc. 83–21190 beginning on page 35349 in the issue of Thursday, August 4, 1983, make the following correction:

On page 35349, third column, under **List of Subjects**, "*7 CFR*" should have read "*8 CFR*".

BILLING CODE 1505-01-M

CIVIL AERONAUTICS BOARD

14 CFR Part 389

Fees and Charges for Special Services

AGENCY: Civil Aeronautics Board.

ACTION: Waiver of Filing-Fee Requirements.

SUMMARY: Following requests on behalf of certain foreign carriers, the Director, Bureau of International Aviation, acting under delegated authority, has waived the requirements of Part 389 of the Board's Organization Regulations to the extent necessary to relieve the carriers of Denmark, Greece, Kuwait, Norway, and Sweden (by letter dated 6/7/83), Colombia (by letter dated 6/7/83), Lebanon (by letter dated 6/22/83), Mali (by letter dated 6/8/83), Jamaica (by letter dated 7/1/83), Western Samoa (by letter dated 7/15/83), Ireland (by letter dated 7/20/83, Saudi Arabia (by letter dated 7/20/83), Yugoslavia (by letter dated 7/21/83), Pakistan (by letter dated 8/2/83), and South Africa (by letter dated 8/10/83), from paying the filing fees set forth in § 389.25.

EFFECTIVE DATE: Each action was effective immediately on the date of the letter and the filing of a petition for review will not alter its effectiveness.

FOR FURTHER INFORMATION CONTACT: Allen Brown, Regulatory Affairs Division, Bureau of International Aviation, Civil Aeronautics Board; (202) 673–5134.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 83-22702 Filed 8-18-83; 8:45 am]

BILLING CODE 6320-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

14 CFR Part 1204

Administrative Authority and Policy

AGENCY: National Aeronautics and Space Administration.

ACTION: Final rule.

SUMMARY: NASA is amending its inspection of persons and personal effects on NASA property, 14 CFR Part 1204 Subpart 10, to conform with its current organization. Since this action is administrative and editorial in nature, notice and public procedure are not required.

EFFECTIVE DATE: August 19, 1983.

ADDRESS: NASA Security Office, Code NIS, NASA Headquarters, Washington, D.C. 20546.

FOR FURTHER INFORMATION CONTACT: Erwin V. Minter, NASA Security Office, Telephone (202) 755–3400.

List of Subjects in 14 CFR Part 1204

Airports, Authority delegations (Government agencies), Federal buildings, Facilities and real estate, Government contracts, Government employees, Government procurement, Grant programs, science and technology, Intergovernmental relations, Labor unions, Security measures, Small businesses.

PART 1204—ADMINISTRATIVE AUTHORITY AND POLICY

For the reason set out in the Preamble, 14 CFR Part 1204 Subpart 10 is revised to read as follows:

Subpart 10—Inspection of Persons and Personal Effects on NASA Property

Sec.

1204.1000 Scope of subpart.
1204.1001 Policy.
1204.1002 Responsibility.
1204.1003 Procedures.

Authority: 42 U.S.C. 2455(a).

Subpart 10—Inspection of Persons and Personal Effects on NASA Property

§ 1204.1000 Scope of subpart.

This subpart establishes NASA policy and prescribes certain minimum procedures concerning the inspection of persons and property in their possession on NASA installations.

§ 1204.1001 Policy.

In the interest of national security, NASA will provide appropriate and adequate protection or security for facilities, property, and information in its possession or custody. In furtherance of this policy, NASA reserves the right to conduct an inspection of any person, including any property in the person's possession or control, as a condition of admission to or continued presence on any NASA installation.

§ 1204.1002 Responsibility.

The Director for each Field Installation and the Director, Headquarters Administration Division, for Headquarters, is responsible for implementing the provisions of this subpart when it is determined that such action is necessary because of bomb threats, unexplained loss of Government property, or other unusual situations, for the protection or security of the installation and the personnel and property therein. In the local implementation of this subpart, the Directors of NASA Installations (and

component installations) located on Federal property under the control of other agencies will coordinate their action with appropriate officials of the other agencies concerned.

§1204.1003 Procedures.

(a) All entrances to NASA installations will be conspicuously posted with the following notice:

PURSUANT TO NASA REGULATIONS THE ENTRANCE OF INDIVIDUALS TO, OR THEIR CONTINUED PRESENCE ON, THIS INSTALLATION IS CONDITIONED UPON THEIR CONSENT TO INSPECTION OF THEIR PERSONS, AND OF PROPERTY IN THEIR POSSESSION OR CONTROL.

(b) Inspection pursuant to this subpart will be conducted only by NASA security personnel or members of the installation security patrol or guard force. Such inspections will be conducted in accordance with guidelines established by the Chief, NASA Security Office, NASA Headquarters.

(c) If an individual does not consent to an inspection, it will not be carried out, and the individual will be denied admission to, or be escorted from, the installation.

(d) If, during an inspection, an individual is found to be in unauthorized possession of items believed to represent a threat to the safety or security of the installation, the individual will be denied admission to, or be escorted from, the installation and appropriate law enforcement authorities will be notified immediately.

(e) If, during an inspection conducted pursuant to this subpart, an individual is in possession of U.S. Government property without proper authorization, that person will be required to relinquish the property to the security representative conducting the inspection pending proper authorization for the possession of the property or its removal from the installation. The individual relinquishing the property will be given a receipt therefor.

James M. Beggs,
Administrator.

[FR Doc. 83-22791 Filed 8-18-83; 8:45 am]
BILLING CODE 7510-01-M

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 210, 229, 231 and 241

[Release Nos. 33-6478; 34-20068; FR-13; File S7-970]

Revision of Industry Guide Disclosures for Bank Holding Companies

AGENCY: Securities and Exchange Commission.

ACTION: Final amendments.

SUMMARY: The Commission authorizes final amendments to its guidelines concerning disclosure by bank holding companies with respect to information about nonaccrual, past due and restructured loans, potential problem loans, foreign outstandings and loan concentrations. The amendments revise the current guidelines dealing with nonperforming loans to focus more broadly on the various risk elements involved in lending activities.

EFFECTIVE DATE: The revisions adopted herein are applicable to filings containing financial statements for fiscal years ending on or after December 31, 1983. Early adoption of these guidelines is encouraged. Upon adoption, the information called for by Item III.C.3. need not be provided for any reported periods ending prior to December 31, 1983 if it is impracticable to do so. Also, the information called for by Item III.C.1. may be presented in accordance with the previous guidelines in Item III.C. for reported periods ending prior to December 31, 1983.

FOR FURTHER INFORMATION CONTACT: Edmund Coulson or Michael P. McLaughlin (202-272-2130), Office of the Chief Accountant, or Howard P. Hodges, Jr. or Henry J. Velsor (202-272-2553), Division of Corporation Finance, Securities and Exchange Commission, Washington, D.C. 20549.

SUPPLEMENTARY INFORMATION:

Executive Summary

This release amends the existing Item III.C., "Nonperforming Loans," of the Industry Disclosure Guides for Bank Holding Companies ("Guide 3") to establish a new section—"Risk Elements."[1] The terminology "nonperforming loans" is no longer utilized in Guide 3. This risk elements section calls for four categories of disclosure:

- Nonaccrual, past due and restructured loans.
- Potential problem loans.
- Foreign outstandings.
- Loan concentrations.

The above information does not have to be set forth in a single table.

The first of the four risk categories contains three of the four classifications of loans which are designated as nonperforming loans in the current Item III.C. of Guide 3, except that the Commission's existing criterion for determining a restructured loan is being replaced by the criteria of Statement of Financial Accounting Standards No. 15 ("FAS 15")[2] for troubled debt restructurings. A significant change in the amended guidelines for disclosure of nonaccrual, past due and restructured loans is the exclusion of certain instructions present in the current Guide which allowed for the use of different criteria, and permitted exclusion of certain loans. This change has the effect of enhancing comparability of disclosures among registrants. Users of this information, particularly financial analysts, have stressed the importance of comparability in this area.

The second category, potential problem loans, is currently the fourth existing criterion for classification of loans as nonperforming (i.e., "serious doubts" loans). These are loans which are not disclosed as part of the first category described above, but where information known by management indicates that the borrower may not be able to comply with present payment terms.

The third category calls for "foreign outstandings" disclosures. This new category is a codification of the substance of the alternative table disclosures of Staff Accounting Bulletin No. 49 ("SAB 49"), "Disclosures by Bank Holding Companies about Certain Foreign Loans" [47 FR 49627, November 2, 1982]. The threshold for disclosure provided in SAB 49, however, has been changed and certain additional disclosures are called for. Certain implementation guidance has also been provided.

The fourth category calls for disclosure of "loan concentrations" which are defined as amounts loaned to a multiple number of borrowers engaged in similar activities which would cause them to be similarly impacted by economic or other conditions. A disclosure threshold of 10% of total loans has been provided.

The Commission believes that these revised guidelines will improve the utility of disclosures by bank holding companies by focusing more broadly on the various risk elements involved in lending activities. Since they require more uniformity in the preparation of the disclosures, the revisions should improve comparability of disclosures among registrants, a factor important to analysts and other users of the data in assessing risk.

[1] The Commission solicited public comments on the proposed revision of Guide 3 in Release No. 33-6462 (April 15, 1983) [48 FR 18826, April 26, 1983]. Forty-nine comment letters were received in response to this proposal.

[2] Financial Accounting Standards Board Statement of Financial Accounting Standards No. 15 "Accounting by Debtors and Creditors for Troubled Debt Restructurings" (June 1977).

As a result of a coordinated effort by the Commission and the Federal banking agencies, the amended guidelines pertaining to "nonaccrual, past due and restructured loans" as well as "foreign outstanding" are consistent with the present and planned disclosure requirements of the Federal banking agencies. Uniformity in the bases for presenting information by bank holding companies in Commission filings and by banks in supplementary disclosures for bank regulatory purposes will reduce compliance burdens and enhance the usefulness of the disclosure reports by investors and the public.

Risk Elements Disclosure

The final guidelines contain a revised format for "Risk Element" disclosures which includes four categories: (1) Non-accrual, past due and restructured loans; (2) potential problem loans; (3) foreign outstandings; and (4) loan concentrations.

A majority of the commentators expressed concerns about the perceived requirement for a tabular format. They were concerned that investors might add all of the amounts disclosed in such a presentation and equate the total to the previously reported "nonperforming loan" amount, and conclude that the risk had increased. The Commission did not intend that the proposed disclosures necessarily be presented in a single tabular format. Registrants may present this data in a manner deemed appropriate to their facts and circumstances provided that such presentation is not misleading.

Rather than adopting the proposal that would have required a breakdown of each of the risk element disclosures by type of loan as set forth in Item III.A. of Guide 3 (loan categories), the final guidelines call for separate disclosure of aggregate foreign and domestic loan amounts only. The proposed display was intended to provide information for assessing relative risks based on the classification of the loan and on the nature of the borrower. This change was made in response to commentators' concerns that such detailed disclosure would be burdensome and complex. However, as discussed later under "Foreign Outstandings," the final amendments call for disclosure of foreign outstandings by type of borrower.

The Commission has adopted a provision for disclosure of potential problem loans which are not reported as "nonaccrual, past due or restructured," but where known information causes management to have serious doubts as to the ability of the borrowers to comply with the present loan repayment terms. "Potential problem loan" information is only required to be presented for the latest reported period. Some commentators asserted that this provision was unnecessary because many such loans may already be reported as nonaccrual in accordance with the registrant's policies. While the Commission understands that the amounts of potential problem loans may not be significant for most registrants because they may place such loans on nonaccrual status, it recognizes there may be difficult judgments as to classification of certain loans and believes that potential problem loans represent material information to investors.

These final amendments add the "foreign outstandings" disclosures to the matters encompassed in the risk elements section in the proposing release. The Commission determined that it is appropriate to include foreign outstandings in the risk elements section in order to embody all risk related disclosure guidelines in one section of the Guide and to emphasize the risks present in cross-border lending activities.

In response to commentators' concerns, the final amendments include a disclosure provision, as an instruction to the "foreign outstandings" category, concerning foreign borrowers whose economic and political conditions are expected to have a material impact on the timely payment of interest or principal. The proposal would have required that "any loans to private and public sector borrowers in foreign countries experiencing economic and political conditions which have created liquidity problems which may have a material impact on the timing of interest or principal payments" be included in the "serious doubts" category. The majority of respondents to the proposal expressed concern that including liquidity-impaired foreign loans in a category of loans which typically comprises credit-impaired loans may be misleading because of the dissimilarity of respective risks. These respondents asserted that any discussion of foreign loans where borrowers may be adversely affected by liquidity problems are best made in the context of disclosures about foreign lending activities.

Many respondents did not concur with the Commission's characterization of industry loan concentrations as a "risk element" because they believed it was inappropriate to present loan concentrations with nonaccrual, past due and restructured loans and other loans as to which there are serious doubts about the ability of the borrower to comply with loan repayment terms. As noted above, loan concentration data would not necessarily have to be presented together with data called for by the other categories of risk elements. The Commission recognizes that the nature of the risks associated with each of the four categories may vary but believes that this can be effectively communicated in registrant filings.

Determination of Certain Risk Elements

The final amendments do not include the substance of certain instructions in the existing Item III.C. which allowed registrants to use different criteria and exclude certain loans in the classification of loans as "nonperforming." The Commission has determined that uniformity in the presentation of this data, and thus comparability among registrants, is important to investors.

Many respondents urged the Commission to retain the substance of the existing Instruction 5 to Item III.C. which provides that "the registrant may use different criteria and may present quantitative information in a different manner than described above if such presentation more effectively identifies and communicates the present risk elements in the loan portfolio.[3] Some respondents urged the Commission to include a similar instruction to provide necessary flexibility in communicating the diversity of lending risks.

Many respondents also urged the Commission to retain the current Instruction 1 to Item III.C. for presentation of past due, nonaccrual and restructured loans. That instruction provided that installment loans to individuals and lease financing amounts may be excluded if the total amount of such loans does not exceed 10% of total loans. These respondents contended that the specific 10% materiality threshold for exclusion should be retained and that data on delinquent consumer loans, if material, should be presented and analyzed separately from data on troubled commercial loans. These persons asserted that consumer delinquencies are not indicative of the same sort of risks as commercial loans because of the nature of the loans and the fact that the accounting convention of automatic charge-off when installment loans reach a certain

[3] The genesis of Instruction 5 to Section III.C. was the initial adoption in 1976 of Guide 3. The intent of this instruction was to provide flexibility in reporting what was then new information about risk elements in the loan portfolio. This instruction was provided since there were varying opinions as to the most appropriate method of determining such elements and the disclosures were in a sense experimental.

delinquency mitigates much of the uncertainty, and therefore risk, normally associated wtih commerical loans.

The Commission is concerned that there has been disparity of practice among registrants in disclosing non-performing loans thereby impacting the comparability of that data. Users who responded to the proposal indicated that risk elements were important indicators and that comparability among registrants is essential. Because the Commission agrees that consistency will enhance the utility of this information to investors, analysts and other users, the substance of Instruction 5 has not been included in the final admendments, and an instruction has been added to the revised Item III.C.1. to specifically prohibit any exclusions. Varying risk elements associated with the types of loans included in the past due, nonaccrual and restructured loan categories may be described in narrative discussions setting forth the reasons for and impact of such factors.

Foregone Interest on Certain Loans

The final guidelines reflect the proposed amendment to include disclosure of interest income that would have been earned under the original loan terms for nonaccrual and restructured loans, and the amounts actually recognized. The proposing release indicated that the amount of interest earned and the amount actually recognized on troubled debt restructurings is an existing financial statement disclosure requirement of FAS 15. The additional disclosure of such amounts related to nonaccrual loans should supplement the disclosures required under generally accepted accounting principles ("GAAP").

Over half of the respondents addressing this point agreed with the proposed disclosures and financial analysts stated that this disclosure was particularly important. Other commentators raised various conceptual objections to any presentation of information representing hypothetical interest that would have been earned by the registrant if the loan had been current. This amendment was adopted because it communicates an element of the cost of carrying certain problem loans, provides supplemental data for nonaccrual loans similar to information already required under GAAP and is an important factor in the estimation of current and potential earning power. Registrants may supplement these disclosures by appropriate textual discussions to the extent they believe necessary to explain the impact of such loans on their operations.

Foreign Outstandings

The Commission has codified the substance of SAB 49's alternative table disclosure for foreign outstandings. Information about foreign outstandings is required for a three-year period rather than the proposed five-year period.

A majority of the commentators responding to the proposal to disclose outstandings to foreign countries in excess of 1% of consolidated outstandings urged retention of the alternatives provided by SAB 49. SAB 49 allows either a tabular presentation of foreign outstandings exceeding 1% or identification of outstandings to foreign countries in excess of 1% where economic or political conditions may impact the timely payment of principal or interest. Many commentators believed that it is not appropriate to require disclosure of outstandings in each country where outstandings exceed 1% of total outstandings because the reader of financial statements could inappropriately interpret this total amount as an unusual risk. Although these commentators generally agreed that there is an additional risk that a foreign government may impose restrictions on funds leaving the country or that foreign exchange may not be available to make timely payments of interest or principal, they did not believe that these risks warranted the type of disclosure proposed by the Commission.

The Commission has carefully considered the views of commentators and has concluded that the proposed table disclosure approach is preferable to one that focuses only on certain countries that are currently experiencing liquidity problems. The amendments adopted herein identify the registrant's significant cross-border exposures in foreign countries and allow investors to arrive at their own conclusions as to any potential or actual transfer risks involved.

The final guidelines call for certain additional disclosures when a foreign country is experiencing liquidity problems because of economic or political conditions which *are expected to have* a material impact on timely payment. This standard implies a greater degree of certainty in determining the impact of such conditions than that of the proposal, viz. when such conditions *may have* an impact on timely payment. The adopted standard should result in greater consistency of disclosures among registrants.

The revised guidelines utilize a disclosure threshold based on total assets. In response to the Commission's inquiry with respect to the propriety of the proposed disclosure threshold of 1% of outstandings, approximately half the respondents stated that the Commission should retain the "consolidated outstandings" threshold measurement for disclosure; slightly less than half of the respondents felt the measurement should be based on consolidated assets; and the remainder believed that the threshold should be based on a percentage of registrants' equity.

The Commission has determined that the use of a threshold based on 1% of total assets has the merit of simplicity of calculation since the total assets amount is readily obtainable from a registrant's balance sheet. In contrast, outstandings typically can not be computed unless supplemental data is furnished. Also, disclosures using a 1% of total assets threshold will be similar to disclosures made pursuant to SAB 49. Finally, in addition to disclosures about individual countries whose outstandings exceed 1% of total assets, the final guidelines (Instruction 7 to Item III.C.3.) call for aggregate disclosures for countries where outstandings are between .75% and 1% of total assets. This disclosure format is consistent with that proposed in the Federal banking agencies' Country Exposure Report.[4]

The proposed separate disclosure of private and public-sector cross-border outstandings has been revised to call for disclosure of outstandings by the types of borrowers specified in Item III.A., i.e., governments and official institutions, banks and other financial institutions, commercial and industrial, and other. Registrants have presented breakdowns similar to that adopted, and users have commented that this level of disclosure is important in assessing a registrant's exposure in certain countries.

The final amendments call for disclosure of outstandings which are repayable in dollars or other non-local currency; they do not require that gross amounts repayable in *local* currency be disclosed. Many commentators asserted that most loans repayable in local currency are substantially funded by local operations and that any net unfunded amounts normally do not reflect significant transfer risk since they generally are not material. The revised guide provides that any material amounts of local currency outstandings which are not hedged or are not funded by local currency borrowings should be reflected in cross-border outstandings.

[4] The Federal banking agencies have announced their intention to provide for increased and more timely disclosures about banks' country exposures. These disclosures would be based on the information called for by the revised Item III.C. of Guide 3 and would be available to the public upon request.

An instruction to Item III.C.3. allows any legally enforceable written guarantees of principal or interest by domestic or other non-local third parties to be netted against the amounts of foreign outstandings presented. The Commission agrees with those respondents who asserted that, when the source of repayment of outstandings is assured by third parties, and the registrant is clearly not exposed to transfer risk because of this recourse, presentation of amounts net of such guarantees more appropriately reflects the registrant's exposure to transfer risks. The amendments also allow collateral values to be netted against the cross-border outstandings of a foreign country in certain limited circumstances.

Several commentators queried whether commitments to lend additional dollar amounts, such as through irrevocable letter of credit agreements, should be included in the determination of "outstandings." Under the revised guide, such commitments would not be included in outstandings, but they would be separately disclosed if material.

In the proposing release, the Commission requested specific comment as to whether a loan to a foreign branch of a foreign bank was or should be reflected as a loan to the foreign country in which the parent bank is located. A substantial majority of those commenting stated that such interbank loans should be reflected as a loan of the parent of the foreign branch. Accordingly, the final amendments include an instruction which indicates that loans made to a branch of a foreign bank located outside the foreign bank's home country should be classified based on the parent's geographic location.

Loan Concentrations

The Commission believes that information about loan concentrations is material information to investors. Accordingly, the final amendments include a requirement to disclose, as of the most recent reported period, any concentration of loans exceeding 10% of total loans. The substance of the concentration disclosure requirement was transferred from the instructions to Item III.A. which calls for disclosure of the categories of loans in the registrant's portfolio. However, concentration disclosures do not have to be made pursuant to the amended Item III.C. if the substance of such disclosures is otherwise made pursuant to Item III.A.

While not intended to indicate levels of prudent lending, the 10% threshold for disclosure of concentrations is intended to provide useful information to investors in evaluating lending portfolios. A 10% threshold has been utilized in other areas in Guide 3 and in Article 9 of Regulation S-X [17 CFR 210.9] for purposes of specifying materiality levels for disclosure purposes.[5]

General guidance is provided in a definition of loan concentrations which states that concentrations are considered to exist when there are amounts loaned to a multiple number of borrowers engaged in similar activities which would cause them to be similarly impacted by economic or other conditions. The definition reflects the objective of this category, i.e., to highlight potential risks when economic or other conditions may result in an adverse impact on the financial condition of the registrant due to concentrated levels of lending activities to borrowers with common characteristics.

As with the other revised guidelines, the Commission staff will monitor disclosures in this area and assess whether additional guidance of a different threshold is appropriate.

Other Matters

The final amendments implement a new Item III.D., which calls for the disclosure of any material amounts of other interest bearing assets (interest bearing deposits with other banks, municipal bonds, etc.) which would be required to be disclosed as past due, nonaccrual or restructured loans, or potential problem loans, if such interest bearing assets were loans.

The final amendments make conforming amendments to Article 9 of Regulation S-X 17 CFR Part 210 and Item 404 of Regulation S-K [17 CFR 229.404] to replace references to "nonperforming" loans with references to those loans described in Item III.C.1. or 2. of Guide 3.

Codification Update

The "Codification of Financial Reporting Policies" announced in Financial Reporting Release No. 1 (April 15, 1982) [47 FR 21028, May 17, 1982] is updated to:

1. Add a new Section 401.08 entitled "Risk Elements Involved in Lending Activities."

2. Include in Section 401.08 the sections of this release entitled "Executive Summary," "Risk Elements Disclosure," "Determination of Certain Risk Elements," "Forgone Interest on Certain Loans," "Foreign Outstandings" and "Loan Concentrations" numbered as specified below:

a. Executive Summary.

b. Risk Elements Disclosure.

c. Determination of Certain Risk Elements.

d. Forgone Interest on Certain Loans.

e. Foreign Outstandings.

f. Loan Concentrations.

This codification is a separate publication issued by the Commission. It will not be published in the **Federal Register**/Code of Federal Regulations System.

List of Subjects in 17 CFR Parts 210, 229, 231 and 241

Accounting, Reporting and recordkeeping requirements, Securities.

The Commission hereby amends 17 CFR Chapter II as follows:

PART 210—FORM AND CONTENT OF AND REQUIREMENTS FOR FINANCIAL STATEMENTS, SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934, PUBLIC UTILITY HOLDING COMPANY ACT OF 1935, INVESTMENT COMPANY ACT OF 1940, AND ENERGY POLICY AND CONSERVATION ACT OF 1975

1. By revising paragraph 7(e)(2) of § 210.9-03 to read as follows:

§ 210.9-03 Balance sheets.

* * * * *

7. Loans. * * *

(e) * * *

(2) If a significant portion of the aggregate amount of loans outstanding at the end of the fiscal year disclosed pursuant to (e)(1)(i) above relates to loans which are disclosed as nonaccrual, past due, restructured or potential problems (see Item III.C. 1. or 2. of Industry Guide 3, Statistical Disclosure by Bank Holding Companies), so state and disclose the aggregate amounts of such loans along with such other information necessary to an understanding of the effects of the transactions on the financial statements.

* * * * *

PART 229—STANDARD INSTRUCTIONS FOR FILING UNDER SECURITIES ACT OF 1933, SECURITIES EXCHANGE ACT OF 1934 AND ENERGY POLICY AND CONSERVATION ACT OF 1975—REGULATION S-K

2. By revising Instruction 3 to paragraph (c) of § 229.404 as follows:

§ 229.404 Item 404. Certain relationships and related transactions.

* * * * *

Instructions to Paragraph (c) of Item 404

* * * * *

3. If the lender is a bank, savings and loan association, or broker-dealer extending credit under Federal Reserve Regulation T [12 CFR Part 220] and the loans are not disclosed as

[5] E.g., see 210.9-05(c)(3), Items III.C. and V.A. of Guide 3.

nonaccrual, past due, restructured or potential problems (see Item III.C. 1. and 2. of Industry Guide 3, Statistical Disclosure by Bank Holding Companies), disclosure may consist of a statement, if such is the case, that the loans to such persons (A) were made in the ordinary course of business, (B) were made on substantially the same terms, including interest rates and collateral, as those prevailing at the time for comparable transactions with other persons, and (C) did not involve more than the normal risk of collectibility or present other unfavorable features.

* * * * *

PART 231—INTERPRETIVE RELEASES RELATING TO THE SECURITIES ACT OF 1933 AND GENERAL RULES AND REGULATIONS THEREUNDER

3. By revising Securities Act Industry Guide 3 [Statistical Disclosure by Bank Holding Companies] of Part 231 by revising the requirements and instructions of Items III.A. and III.C., and by adding new Item III.D.

* * * * *

III. Loan Portfolio.

* * * * *

A. *Types of Loans.*

* * * * *

Instructions. A series of categories other than those specified above may be used to present details of loans if considered a more appropriate presentation.

* * * * *

B. *Maturities and Sensitivities of Loans to Changes in Interest Rates.*

* * * * *

C. *Risk Elements.*

1. *Nonaccrual, Past Due and Restructured Loans.* As of the end of each reported period, state separately the aggregate amount of loans in each of the following categories:

(a) Loans accounted for on a nonaccrual basis;

(b) Accruing loans which are contractually past due 90 days or more as to principal *or* interest payments; and,

(c) Loans not included above which are "troubled debt restructurings" as defined in Statement of Financial Accounting Standards No. 15 ("FAS 15"), "Accounting by Debtors and Creditors for Troubled Debt Restructurings."

Instructions. (1) The information required by this Item should be provided separately for domestic and for foreign loans for each reported period.

(2) As of the most recent reported period, state separately as to foreign and domestic loans included in (a) and (c) above the following information: (i) the gross interest income that would have been recorded in the period then ended if the loans had been current in accordance with their original terms and had been outstanding throughout the period or since origination, if held for part of the period; and (ii) the amount of interest income on those loans that was included in net income for the period.

(3) A discussion of the registrant's policy for placing loans on nonaccrual status should be provided.

(4) No loans shall be excluded from the amounts presented. Supplemental disclosures may be made to facilitate understanding of the aggregate amounts reported. These disclosures may include, for example, information as to the nature of the loans, any guarantees, the extent of collateral, or amounts in process of collection.

2. *Potential Problem Loans.* As of the end of the most recent reported period, describe the nature and extent of any loans which are not now disclosed pursuant to Item III.C.1. above, but where known information about possible credit problems of borrowers (which are not related to transfer risk inherent in cross-border lending activities) causes management to have serious doubts as to the ability of such borrowers to comply with the present loan repayment terms and which may result in disclosure of such loans pursuant to Item III.C.1.

3. *Foreign Outstandings.* As of the end of each of the last three reported periods, state the name of the country and aggregate amount of cross-border outstandings to borrowers in each foreign country where such outstandings exceed 1% of total assets.

Instructions. (1) Cross-border outstandings are defined as loans (including accrued interest), acceptances, interest-bearing deposits with other banks, other interest-bearing investments and any other monetary assets which are denominated in dollars or other non-local currency. To the extent that material local currency outstandings are not hedged or are not funded by local currency borrowings, such amounts should be included in cross-border outstandings. Commitments such as irrevocable letters of credit should not be included in outstandings; however, where such items are material, the amounts should be separately disclosed.

(2) Disclose separately the amounts of cross-border outstandings by type of foreign borrower as set forth in Item III.A. above.

(3) If a material amount of the outstandings to any foreign country disclosed herein is included in the amounts disclosed pursuant to Item III.C.1. or 2. identify each such country and the related amounts disclosed pursuant to those Items.

(4) Amounts of any legally enforceable, written guarantees of principal or interest by domestic or other non-local third parties may be netted against cross-border outstandings of a country. If such a guarantee is made by a foreign guarantor, the guarantee amount shall be reflected as an outstanding of such guarantor. The value of any tangible, liquid collateral may also be netted against cross-border outstandings of a country if it is held and realizable by the lender outside of the borrower's country.

(5) For purposes of determining the amount of outstandings to be reported, loans made to, or deposits placed with, a branch of a foreign bank located outside the foreign bank's home country should be considered as loans to, or deposits with, the foreign bank.

(6) Where current conditions in a foreign country give rise to liquidity problems which are expected to have a material impact on the timely payment of interest or principal on that country's private or public sector debt, disclosure of the nature and impact of such developments should be made.

(7) For countries whose outstandings are between .75% and 1% of total assets, disclose the names of the countries and the aggregate amount of outstandings attributable to all such countries.

(8) The disclosure threshold set forth in this Item is for disclosure guidance and is not intended as an indicator of a prudent level of lending to any one country by an individual bank.

4. *Loan Concentrations.* As of the end of the most recent reported period, describe any concentration of loans exceeding 10% of total loans which are not otherwise disclosed as a category of loans pursuant to Item III.A. of this Guide. Loan concentrations are considered to exist when there are amounts loaned to a multiple number of borrowers engaged in similar activities which would cause them to be similarly impacted by economic or other conditions. *Instructions.* (1) If a material amount of the loan concentrations disclosed herein or pursuant to Item III.3A. is included in the amounts disclosed pursuant to Item III.C.1. or 2., that fact should be discussed.

(2) The disclosure threshold in this Item is for disclosure guidance and is not intended as an indicator of a prudent level of lending.

D. *Other Interest Bearing Assets.* As of the end of the most recent reported period, disclose the nature and amounts of any other interest bearing assets that would be required to be disclosed under Item III.C.1. or 2. if such assets were loans.

4. By amending Part 231 by adding this release number to the list of interpretive releases set forth thereunder.

PART 241—INTERPRETIVE RELEASES RELATING TO THE SECURITIES EXCHANGE ACT OF 1934 AND GENERAL RULES AND REGULATIONS THEREUNDER

5. By conforming Exchange Act Industry Guide 3 [Statistical Disclosure by Bank Holding Companies] to the amendments for Securities Act Industry Guide 3.

6. By amending Part 241 by adding this release number to the list of interpretive releases set forth thereunder.

Authority: These rules are being adopted pursuant to the authority in Sections 7, 19a, and Schedule A (25) and (26) of the Securities Act of 1933, 15 U.S.C. 77g, 77s(a), 77nn (25) and (26); and Sections 12, 13, 14, 15(d), and 23(a) of the Securities Exchange Act of 1934, 15 U.S.C. 78*l*, 78m, 78n, 78o(d), 78w(a).

By the Commission.

Dated: August 11, 1983.

George A. Fitzsimmons,

Secretary.

[FR Doc. 83-22768 Filed 8-18-83; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 81F-0197]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Dimethylamine-Epichlorohydrin Copolymer

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the use of dimethylamine-epichlorohydrin copolymer for use as a flocculant and/or decolorizer in the clarification of refinery sugar liquors and juices. This action is in response to a petition filed by American Cyanamid Co.

DATES: Effective August 19, 1983; objections by September 19, 1983. The Director of the **Federal Register** approves the incorporation by reference of certain publications at 21 CFR 173.60, effective on August 19, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 21, 1981 (46 FR 37565), FDA announced that a petition (FAP OA3500) had been filed by American Cyanamid Co., Wayne, NJ 07470, proposing that Part 173 (21 CFR Part 173) be amended in Subpart A—Polymer Substances for Food Treatment—to provide for safe use of dimethylamine-epichlorohydrin copolymer for use as a flocculant and/or decolorizer in clarifying refinery-sugar liquors and juices.

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additive use is safe and that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact and the evidence supporting this finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 173

Food additives, Food processing aids.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 173 is amended in Subpart A by adding new § 173.60, to read as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

§ 173.60 Dimethylamine-epichlorohydrin copolymer.

Dimethylamine-epichlorohydrin copolymer (CAS Reg. No. 25988-97-0) may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by copolymerization of dimethylamine and epichlorohydrin in which not more than 5 mole-percent of dimethylamine may be replaced by an equimolar amount of ethylenediamine, and in which the mole ratio of total amine to epichlorohydrin is approximately 1:1.

(b) The additive meets the following specifications:

(1) The nitrogen content of the copolymer is 9.4 to 10.8 weight percent on a dry basis.

(2) A 50-percent-by-weight aqueous solution of the copolymer has a minimum viscosity of 175 centipoises at 25° C as determined by LVT-series Brookfield viscometer using a No. 2 spindle at 60 RPM (or by another equivalent method).

(3) The additive contains not more than 1,000 parts per million of 1,3-dichloro-2-propanol and not more than 10 parts per million epichlorohydrin. The epichlorohydrin and 1,3-dichloro-2-propanol content is determined by an analytical method entitled "The Determination of Epichlorohydrin and 1,3-Dichloro-2-Propanol in Dimethylamine-Epichlorohydrin Copolymer," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Bureau of Foods (HFF-330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(4) Heavy metals (as Pb), 2 parts per million maximum.

(5) Arsenic (as As), 2 parts per million maximum.

(c) The food additive is used as a decolorizing agent and/or flocculant in the clarification of refinery sugar liquors and juices. It is added only at the defecation/clarification stage of sugar liquor refining at a concentration not to exceed 150 parts per million of copolymer by weight of sugar solids.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by the act, adequate directions to assure use in compliance with paragraph (c) of this section.

Any person who will be adversely affected by the foregoing regulation may at any time on or before September 19, 1983, submit to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and anslysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective August 19, 1983.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: August 13, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-22775 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 175 and 178

[Docket No. 82F-0055]

Indirect Food Additives; Adhesive Coatings and Components; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2,2'- oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)-propionate] as an antioxidant and/or stabilizer in polystyrene, rubber-modified polystyrene, olefin polymers, and as a component in adhesive formulations. Uniroyal Chemical Co. petitioned for this use.

DATES: Effective August 19, 1983; objections by September 19, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Garnett R. Higginbotham, Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of March 30, 1982 (47 FR 13413), FDA announced that a petition (FAP 2B3592) had been filed by Uniroyal Chemical, Naugatuck, CT 06770, proposing that the food additive regulations be amended to provide for the safe use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxphenyl)- propionate] as an antioxidant and/or stabilizer in polystyrene, rubber-modified polystyrene, olefin polymers, and as a component in adhesive formulations.

Although the food additive has not, itself, been found to induce cancer, it may contain trace amounts of a carcinogenic compound, which is used in the manufacture of the additive. Residual amounts of reactants and manufacturing aids are commonly found as contaminants in all chemical products, even in highly purified reagent grade chemicals, including many food additives.

Under section 409(c)(3)(A) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless the data presented to FDA establish that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 was explained in the legislative history of that provision. "Safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive. It does not—and cannot—require proof beyond any possible doubt that no harm will result under any conceivable circumstances." H. R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958). This definition of safety has been incorporated into FDA's food additive regulations (21 CFR 170.3(i)). The anticancer or Delaney clause of the food additives amendment (section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A))) provides further that no food additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal.

In the past, FDA has generally interpreted the food additive provisions to ban the use of any additive that contained or was suspected of containing minor amounts of a carcinogenic chemical, even if the additive as a whole had not been shown to cause cancer. The agency now believes, however, that developments in scientific technology and experience with risk assessment procedures make it possible for FDA validly to distinguish between carcinogenic additives and those that contain a carcinogenic chemical, but that have not themselves been shown to cause cancer. Buttressing that scientific conclusion is the 1979 decision in *Monsanto* v. *Kennedy*, 613 F.2d 947 (D.C. Cir. 1979) in which the court expressed the view that the Commissioner of Food and Drugs has some discretion, inherent in the statute, to disregard low-level migration into food of substances in indirect food additives because the migration of the substance presents no public health concern. *Id.* at 955.

In the preamble to the final rule permanently listing D&C Green No. 6 published in the **Federal Register** of April 2, 1982 (47 FR 14138), FDA applied that interpretation of the statute and approved the use of a color additive that had not been shown to cause cancer, even though it contains a carcinogenic constituent. Since that decision, FDA has approved the use of 3 such color additives, D&C Green No. 5 (47 FR 24278; June 4, 1982) and D&C Red No. 6 and D&C Red No. 7 (47 FR 57681; December 28, 1982). FDA fully explained the scientific, legal, and policy underpinning for such decisions in the policy for regulating carcinogenic chemicals in food and color additives advance notice of proposed rulemaking (ANPR) published in the **Federal Register** of April 2, 1982 (47 FR 14464). In brief, the agency now believes that the Delaney or anti-cancer clause is not triggered unless the food additive as a whole is found to cause cancer. An additive that has not been shown to cause cancer but that contains a carcinogenic constituent may properly be evaluted under the general safety clause of the statute, using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive. Because 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] has not been shown to cause cancer, the anti-cancer clause does not apply. FDA has evaluated the safety of this additive under the general safety clause, using risk assessment procedures to estimate the upper bound limit risk presented by the carcinogenic chemical present as an impurity in the additive, and has concluded that the additive is safe under the proposed conditions of use.

This final rule approves the use of the additive and discusses the safety assessment of the additive and its constituent. The identity of the constituent, however, is confidential under section 301(j) of the act (21 U.S.C. 331(j) and 21 CFR 171.1(h)(2)) because it is a trade secret. Accordingly, although the agency has performed a full risk assessment of the type discussed in the ANPR (47 FR at 14468–14469), this document will discuss that assessment only in general terms so as to avoid divulging information that is protected from disclosure under 21 U.S.C. 331(j) and 21 CFR 20.61.

In this case, the agency has used risk assessment procedures similar to the methods used to examine the risk associated with the presence of minor carcinogenic impurities in D&C Green No. 6 (47 FR 14138; April 2, 1982), D&C Green No. 5 (47 FR 24278; June 4, 1982), and D&C Red No. 6 and D&C Red No. 7 (47 FR 57681; December 28, 1982).

This risk evaluation of the carcinogenic constituent consists of two parts: (1) Assessment of the probable exposure to the constituent from the proposed use of the additive, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of probable exposure to humans.

FDA estimated the probable exposure to the constituent from extraction studies, taking into account what fraction of the daily diet might be packaged in materials containing the additive. FDA has used data from carcinogenicity bioassays in which the constituent at issue was administered in the diet of rats and mice to estimate the upper level of human risk from exposure to it stemming from the proposed use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate]. The results of the bioassay of the constituent indicated compound-related increases in the incidence of certain tumors in male and female mice (the rat study was negative).

The agency used a quantitative risk assessment procedure (linear proportional model) to extrapolate from the dose in the animal experiment to the very low doses of possible human exposure. This procedure is not likely to underestimate the actual risk from very low doses. In fact, the estimate of the risk may be exaggerated because the extrapolation models used are designed to estimate the maximum risk consistent with the data. For this reason, the estimate can be used with confidence to determine to a reasonable certainty whether any harm will result from the use of this food additive. Under this procedure, the upper limit individual lifetime risk from exposure to the constituent at the level calculated to be the estimated daily intake is 7×10^{-8} or less than 1 in 10 million. Because of numerous conservatisms in the exposure estimate, lifetime-averaged individual exposure is expected to be substantially less than the estimated daily intake. Thus, the agency concludes that there is a reasonable certainty of no harm from the exposure to the constituent that results from the use of 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl) propionate].

The petitioner has submitted the results of several studies to demonstrate that there is a reasonable certainty of no harm from the intended use of the additive. These studies include acute oral toxicity studies (LD_{50} in rats and a 14-day maximum tolerated dose study in dogs), an Ames-type mutagenicity test, and 90-day (subchronic) feeding studies in rats and dogs. The LD_{50} in rats is greater than 10 grams per kilogram. The mutagenicity test was negative. No tissue abnormalities or other compound-related adverse effects were observed in either the dog or rat feeding studies over the range of doses tested. Based on these studies and using a safety factor of 1,000, considered appropriate by the agency for subchronic studies, the agency has established an acceptable daily intake of 0.5 milligram per kilogram of body weight per day or 30 milligrams per day for a 60 kilogram person.

The agency has calculated an estimated daily intake based on considerations such as migration of the additive under maximum intended use conditions into food simulants and estimates of the probable fraction of the daily diet that packaging containing the subject additive may contact. The estimated daily intake for 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl) propionate] under the intended use conditions is 0.6 milligram per day for a 60 kilogram person. This is 50 times less than the acceptable daily intake.

The agency has considered whether a specification is necessary to control the amount of the constituent that might migrate to food. The agency finds that a specification is not necessary for the following reasons: (1) The upper limit lifetime risk from exposure to the constituent is very low; (2) use of the additive is limited to 0.5 percent or less of a formulation, except for use of the additive in adhesives, where migration to food is expected to be much less than migration from the regulated polymeric food-contact surfaces; and (3) when used in accordance with current good manufacturing practice, it is unlikely that significantly higher amounts of the constituent would be used in the manufacture of this additive.

Based upon the available toxicity data, the agency's exposure calculation for the additive, and the very low risk from the potential carcinogenic impurity, FDA finds that the food additive 2,2'-oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl) propionate] is safe and that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents including the risk assessment that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact and the evidence supporting this finding, contained in an environmental assessment (pursuant to 21 CFR 25.31, proposed December 11, 1979; 44 FR 71742,) may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Parts 175 and 178 are amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVE COATINGS AND COMPONENTS

1. Part 175 is amended in § 175.105(c)(5) by alphabetically inserting a new item in the list of substances, to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
2,2'-Oxamidobis[ethyl 3-(3,5-di-*tert*-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331-94-1).	
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PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

2. Part 178 is amended in § 178.2010(b) by alphabetically inserting a new item in the list of substances, to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * * *	
2,2'-Oxamidobis[ethyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate] (CAS Reg. No. 70331-94-1).	For use only: 1. At levels not to exceed 0.5 percent by weight of polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter. 2. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, and 1.3. 3. At levels not to exceed 0.5 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, and 4.0 that contact food types I, II, IV-B, VI, VII-B and VIII described in Table 1 of § 176.170(c) of this chapter. 4. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, and 4.0 that contact food types III, IV-A, V, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter; except that olefin copolymers complying with items 3.1 and 3.2 where the majority of polymer units are derived from propylene may contain the additive at levels not to exceed 0.5 percent. 5. At levels not to exceed 0.1 percent by weight of olefin polymers complying with item 3.4 of § 177.1520(c) of this chapter, that contact food types III, VII-A, and IX described in Table 1 of § 176.170(c) of this chapter; except that olefin copolymers complying with item 3.4 where the majority of the polymer units are derived from polypropylene may contain the additive at levels not to exceed 0.5 percent.
* * * * *	

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Any person who will be adversely affected by the foregoing regulation may at any time on or before September 19, 1983, submit to the Dockets Management Branch (address above), written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation becomes effective August 19, 1983.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: August 13, 1983.

Mark Novitch,

Acting Commissioner of Food and Drugs.

[FR Doc. 83-22778 Filed 8-18-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 176

[Docket No. 82F-0087]

Indirect Food Additives; Paper and Paperboard Components; Components of Paper and Paperboard in Contact With Aqueous and Fatty Foods

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regualtions by removing the upper viscosity limit of a currently regulated retention aid. The retention aid is polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture. This action responds to a petition filed by Sandoz Colors and Chemicals.

DATES: Effective August 19, 1983; objections by September 19, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John L. Herrman, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of April 9, 1982 (47 FR 15411), FDA announced that a petition (FAP 2B3622) had been filed by Sandox Colors and Chemicals, East Hanover, NJ 07936, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended by removing the upper viscosity limit of a currently regulated retention aid. The retention aid is polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid with diethylenetriamine to form a basic polyamide and further reacting the polyamide with an epichlorohydrin and dimethylamine mixture.

FDA has evaluated data in the petition and other relevant material and concludes that the proposed removal of the upper viscosity limit will not affect the safety of the currently regulated product and that the regulation should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2) (21 CFR 171.1(h)(2)), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the potential environmental effects of this regulation as announced in the notice of filing published in the **Federal Register.** No new information or comments have been received that would alter the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting this finding may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging, Paper and paperboard.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 176 is amended in § 176.170(a)(5) by revising the entry for "Polyamide-epichlorohydrin water-soluble thermosetting resins prepared by reacting adipic acid with diethylenetriamine", to read as follows: