FOR FURTHER INFORMATION CONTACT: Jennifer J. Johnson, Secretary of the Board (202/452–3259); for users of Telecommunications Device for the Deaf (TDD), please contact Diane Jenkins, (202/452–3544), Board of Governors of the Federal Reserve System, 20th and C Streets N.W., Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION: Pursuant to the authority of sections 10(b), 13, 14, 19, et. al., of the Federal Reserve Act, the Board has amended its Regulation A (12 CFR part 201) to incorporate changes in discount rates on Federal Reserve Bank extensions of credit. The discount rates are the interest rates charged to depository institutions when they borrow from their district Reserve Banks.

The ''basic discount rate'' is a fixed rate charged by Reserve Banks for adjustment credit and, at the Reserve Banks' discretion, for extended credit. In decreasing the basic discount rate, the Board acted on requests submitted by the Boards of Directors of the twelve Federal Reserve Banks. The new rates were effective on the dates specified below. Growing caution by lenders and unsettled conditions in financial markets more generally are likely to be restraining aggregate demand in the future. Against this backdrop, further easing of the stance of monetary policy was judged to be warranted to sustain economic growth in the context of contained inflation.

Regulatory Flexibility Act Certification

Pursuant to section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Board certifies that the change in the basic discount rate will not have a significant adverse economic impact on a substantial number of small entities. The rule does not impose any additional requirements on entities affected by the regulation.

Administrative Procedure Act

The provisions of 5 U.S.C. 553(b) relating to notice and public participation were not followed in connection with the adoption of the amendment because the Board for good cause finds that delaying the change in the basic discount rate in order to allow notice and public comment on the change is impracticable, unnecessary, and contrary to the public interest in fostering sustainable economic growth.

The provisions of 5 U.S.C. 553(d) that prescribe 30 days prior notice of the effective date of a rule have not been followed because section 553(d) provides that such prior notice is not necessary whenever there is good cause for finding that such notice is contrary to the public interest. As previously stated, the Board determined that delaying the changes in the basic discount rate is contrary to the public interest.

List of Subjects in 12 CFR Part 201

Banks, banking, Credit, Federal Reserve System.

For the reasons set out in the preamble, 12 CFR Part 201 is amended as set forth below:

PART 201—EXTENSIONS OF CREDIT BY FEDERAL RESERVE BANKS (REGULATION A)

1. The authority citation for 12 CFR part 201 continues to read as follows:

Authority: 12 U.S.C. 343 *et seq.*, 347a, 347b, 347c, 347d, 348 *et seq.*, 357, 374, 374a and 461.

2. Section 201.51 is revised to read as follows:

§ 201.51 Adjustment credit for depository institutions.

The rates for adjustment credit provided to depository institutions under § 201.3(a) are:

Federal reserve bank	Rate	Effective
Boston	4.75	October 15, 1998.
New York	4.75	October 15, 1998.
Philadelphia	4.75	October 15, 1998.
Cleveland	4.75	October 16, 1998.
Richmond	4.75	October 16, 1998.
Atlanta	4.75	October 15, 1998.
Chicago	4.75	October 15, 1998.
St. Louis	4.75	October 15, 1998.
Minneapolis	4.75	October 15, 1998.
Kansas City	4.75	October 15, 1998.
Dallas	4.75	October 16, 1998.
San Francisco	4.75	October 15, 1998.

By order of the Board of Governors of the Federal Reserve System, October 19, 1998.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 98–28499 Filed 10–22–98; 8:45 am]

BILLING CODE 6210–01–P

SMALL BUSINESS ADMINISTRATION

13 CFR Parts 121 and 125

Small Business Size Regulations and Government Contracting Assistance Regulations; Very Small Business Concern

AGENCY: Small Business Administration (SBA).

ACTION: Final rule; notice of compliance date.

SUMMARY: The Small Business Administration published a final rule implementing its Very Small Business Set-Aside Pilot Program in the **Federal Register** of September 2, 1998 (63 FR 46640). In this document the SBA establishes a compliance date of January 4, 1999.

DATES: The compliance date for the Final Rule published at 63 FR 46640 is January 4, 1999.

FOR FURTHER INFORMATION CONTACT: Anthony Robinson, Office of Prime Contracting, at (202) 205–6126.

SUPPLEMENTARY INFORMATION: The Small Business Administration (SBA) published a final rule in the **Federal Register** on September 2, 1998 (63 FR 46640), implementing its Very Small Business (VSB) Set-Aside Pilot Program. The effective date of that rule was September 2, 1998. SBA has determined that it would be in the best interests of those small entities served by the VSB program and those agencies required to implement this program, to establish a compliance date for this rule of January 4, 1999. This will facilitate the promulgation of Government-wide procurement regulations in the Federal Acquisition Regulation (FAR) and, will ensure uniform application and implementation of SBA's VSB program by all Federal agencies. These FAR regulations will be published in the form of an Interim Rule in the **Federal Register** on or before January 4, 1999. Should publication of procurement regulations be delayed in the FAR, the compliance date of this rule will remain as January 4, 1999 and SBA will supply guidance for the implementation of this rule, to those agencies affected, through its Procurement Center Representatives.

Dated: October 15, 1998.

Aida Alvarez,

Administrator.

[FR Doc. 98–28422 Filed 10–22–98; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 98F–0433]

Indirect Food Additives: Adhesives and Components of Coatings

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polyethylene glycol mono-isotridecyl ether sulfate, sodium

salt as a surfactant in adhesives intended for use in contact with food. This action is in response to a petition filed by Servo Delden BV.

DATES: This regulation is effective October 23, 1998; submit written objections and requests for a hearing by November 23, 1998.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 30, 1998 (63 FR 35603), FDA announced that a food additive petition (FAP 8B4600) had been filed by Servo Delden BV, c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 175.105 *Adhesives* (21 CFR 175.105) to provide for the safe use of polyethylene glycol mono-isotridecyl ether sulfate, sodium salt as a surfactant in adhesives intended for use in contact with food.

In its evaluation of the safety of this additive, FDA has reviewed the safety of the additive itself and the chemical impurities that may be present in the additive resulting from its manufacturing process. Although the additive itself has not been shown to cause cancer, it has been found to contain minute amounts of unreacted 1,4-dioxane and ethylene oxide, carcinogenic impurities resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as 1,4-dioxane and ethylene oxide, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

Under the so-called ''general safety clause'' of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A)), a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe for that use. FDA's food additive regulations (21 CFR 170.3(i)) define safe as ''a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.''

The food additives anticancer, or Delaney, clause of the act (21 U.S.C. 348(c)(3)(A)) provides that no food additive shall be deemed safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the additive itself and not to impurities in the additive. That is, where an additive itself has not been shown to cause cancer, but contains a carcinogenic impurity, the additive is properly evaluated under the general safety standard using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the additive (*Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984)).

II. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, polyethylene glycol mono-isotridecyl ether sulfate, sodium salt as a surfactant in adhesives will result in exposure to no greater than 7 parts per billion (ppb) of the additive in the daily diet (3 kilogram (kg)) or an estimated daily intake of 21 microgram per person per day (μg/p/d) (Ref. 1).

FDA does not ordinarily consider chronic toxicological studies to be necessary to determine the safety of an additive whose use will result in such low exposure levels (Ref. 2), and the agency has not required such testing here. However, the agency has reviewed the available toxicological data on the additive and concludes that the estimated small dietary exposure resulting from the petitioned use of the additive is safe.

FDA has evaluated the safety of this additive under the general safety standard, considering all available data and using risk assessment procedures to estimate the upper-bound limit of lifetime human risk presented by 1,4-dioxane and ethylene oxide, the carcinogenic chemicals that may be present as impurities in the additive. This risk evaluation of 1,4-dioxane and ethylene oxide has two aspects: (1) Assessment of the exposure to the impurities from the proposed use of the additive, and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. 1,4-Dioxane

FDA has estimated the exposure to 1,4-dioxane from the petitioned use of the additive in adhesives to be 0.2 ppb of the daily diet (3 kg) or 0.6 μg/p/d (Ref. 1). The agency used data from a carcinogenesis bioassay on 1,4-dioxane, conducted by the National Cancer Institute (Ref. 3), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the proposed use of the additive. The results of the bioassay on 1,4-dioxane demonstrated that the test material caused significantly increased incidence of squamous cell carcinomas and hepatocellular tumors in female rats.

Based on the agency's estimate that exposure to 1,4-dioxane will not exceed 0.6 μg/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the proposed use of the subject additive is 2.1×10^{-8} (or 2.1 in 100 million) (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to 1,4-dioxane is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to 1,4-dioxane would result from the proposed use of the additive.

B. Ethylene Oxide

FDA has estimated the exposure to ethylene oxide from the petitioned use of the additive in adhesives to be 5 parts per trillion in the daily diet (3 kg) or 15 nanograms (ng)/p/d (Ref. 1). The agency used data from a carcinogenesis bioassay on ethylene oxide conducted by the Institute of Hygiene, University of Mainz, Germany (Ref. 5), to estimate the upper-bound limit of lifetime human risk from exposure to ethylene oxide resulting from the proposed use of the additive. The results of the bioassay on ethylene oxide demonstrated that the test material caused significantly increased incidence of squamous cell carcinomas of the forestomach and carcinomas of the glandular stomach in female rats.

Based on the agency's exposure estimate to ethylene oxide of 15 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the proposed use of the subject additive is 2.8×10^{-8} (or 2.8 in 100 million)) (Ref. 4). Because of the numerous conservative assumptions used in calculating the exposure estimate, the actual lifetime-averaged individual exposure to ethylene oxide is likely to be substantially less than the estimated exposure, and therefore, the probable lifetime human risk would be less than the upper-bound limit of lifetime human risk. Thus, the agency concludes that there is reasonable certainty that no harm from exposure to ethylene oxide would result from the proposed use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of 1,4-dioxane and ethylene oxide as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which 1,4-dioxane and ethylene oxide may be expected to remain as impurities following production of the additives, the agency would not expect the impurities to become components of food at other than extremely small levels; and (2) the upper-bound limits of lifetime risk from exposure to 1,4-dioxane and ethylene oxide is very low, 2.1 in 100 million and 2.8 in 100 million, respectively.

III. Conclusion

FDA has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive in adhesives is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 175.105 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 Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 8B4600 (June 30, 1998, 63 FR 35603). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before November 23, 1998, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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 document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from the Chemistry Review Team, FDA, to the file concerning FAP 8B4600 (MATS No. 978, M2.0 & 2.1), Servo Delden BV, use of polyethylene glycol mono-isotridecyl ether sulfate sodium salt as a component of adhesives, dated July 16, 1998.

2. Kokoski, C. J., ''Regulatory Food Additive Toxicology,'' in *Chemical Safety Regulation and Compliance*, edited by F. Homburger, and J. K. Marquis, published by S. Karger, New York, NY, pp. 24–33, 1985.

3. ''Bioassay of 1,4-Dioxane for Possible Carcinogenicity,'' National Cancer Institute, NCI–CG–TR–80, 1978.

4. Memorandum from the Indirect Additives Branch, FDA, to the Executive Secretary, Quantitative Risk Assessment Committee, FDA, concerning ''Estimation of upper-bound lifetime risk from ethylene oxide and 1,4-dioxane in polyethylene glycol mono-isotridecyl ether sulfate, sodium salt as a surfactant in adhesives: Food Additive petition No. 8B4600 (Servo Delden BV),'' dated July 22, 1998.

5. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2-propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46: pp. 924–933, 1982.

List of Subjects in 21 CFR Part 175

Adhesives, Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 175.105 is amended in the table in paragraph (c)(5) by alphabetically adding an entry under the heading ''Substances'' to read as follows:

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * * * *	
Polyethylene glycol mono-isotridecyl ether sulfate, sodium salt (CAS Reg. No. 150413–26–6).	
* * * * * * *	

Dated: October 15, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28410 Filed 10–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F–0164]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations for the use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. When the regulation was last amended, the agency inadvertently omitted the limitation on the use level for the additive. This document corrects that inadvertent omission.

EFFECTIVE DATE: October 23, 1998.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of December 16, 1996 (61 FR 65942), FDA published a document amending the food additive regulations to provide for the expanded safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. The limitation added by this document was inadvertently omitted from the December 16, 1996, final rule due to an administrative error. Limiting the use level of the additive to no more than 0.30 percent by weight of the olefin polymers is supported by the administrative record of the final rule. Accordingly, FDA is amending the regulation to accord with the record.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.3295 is amended in the table in the entry for ''Sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate'' by revising entry ''3.'' under the heading ''Limitations'' to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
* * *	* * * *
Sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate (CAS Reg. No. 85209–91–2)	For use only: * * * * * 3. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, where the finished polymer contacts food only of types I, II, IV–B, VI–A, VI–B, and VII–B as identified in Table 1 of § 176.170(c) of this chapter, and limited to conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, or foods of types III, IV–A, V, VI–C, and VII–A as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.

Dated: October 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28409 Filed 10–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 77N–094W]

Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to require an alcohol warning for all over-the-counter (OTC) drug products, labeled for adult use, containing internal analgesic/antipyretic active ingredients. The required warning statements advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. FDA is issuing this final rule after considering comments on the agency's proposed regulation for OTC internal analgesic, antipyretic, and antirheumatic drug products; a proposed regulation to establish an alcohol warning; recommendations of its Nonprescription Drugs Advisory Committee (NDAC) and Arthritis Drugs Advisory Committee (ADAC); and new data and information that have come to the agency's attention. This final rule is part of the ongoing