Administrator, subject to such limitations as the Administrator may prescribe.

(b) The Board shall have the power to approve, authorize or direct any action, including the modification or release of any obligations, and to make determinations and findings which are necessary or appropriate for the conduct of its functions, and may adopt such rules of procedure as it considers desirable.

(c) The concurring vote of a majority of the total Board membership shall constitute an action of the Board. Decisions of the Board shall be final but the Board may reconsider and modify, correct or reverse any Board decision previously made.

§ 1209.304 Membership.

The Board will consist of a chairperson and four other members, all of whom shall be appointed by the Administrator.

§ 1209.305 Legal advice and assistance.

The General Counsel of NASA shall provide the Board with all necessary advice and assistance.

James C. Fletcher,

Administrator.

[FR Doc. 86-18168 Filed 8-12-86; 8:45 am]

BILLING CODE 7510-01-M

DEPARTMENT OF COMMERCE

15 CFR Part 20

[Docket No. 60467-6067]

Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance

AGENCY: Department of Commerce.

ACTION: Final rule.

SUMMARY: The Department of Commerce (DOC) is required to issue regulations implementing the Age Discrimination Act (Act) of 1975, as amended. The DOC is issuing specific regulations to carry out this responsibility which will apply to all entities within the Department that administer programs of Federal financial assistance. The Act prohibits discrimination on the basis of age in programs or activities receiving Federal financial assistance. It contains certain exceptions which permit, under limited circumstances, continued use of age distinctions or factors other than age which may have a disproportionate effect on a particular age group. The Act excludes from its coverage most employment practices. The Department of Commerce has no statutory, regulatory or administrative age distinctions; however, we must ensure that adequate and effective protection is provided for any person who may have a compliant under this statute.

EFFECTIVE DATE: September 12, 1986.

FOR FURTHER INFORMATION CONTACT: Arthur E. Cizek, Chief, Compliance Division, Office of Civil Rights, U.S. Department of Commerce, Washington, DC 20230, (202) 377-4993.

SUPPLEMENTARY INFORMATION: The history of the Act can be found in the background section of the general regulations issued by the Department of Health, Education and Welfare (HEW), now the Department of Health and Human Services (HHS), to implement the Act and to guide the development of each agency's specific regulations. *See* 44 FR 33768 (June 12, 1979). The Act is designed to prohibit discrimination on the basis of age in programs or activities which receive Federal financial assistance. The Act also contains certain exceptions which permit, under certain circumstances, age distinctions and factors other than age to continue in use. The Act applies to persons of all ages.

Proposed DOC regulations were published at 45 FR 46437 on July 10, 1980. No comments were received relative to those proposed regulations. The final rules were cleared by HHS on September 10, 1985, as consistent with their final regulations with no revisions necessary.

Although the Act generally covers all programs and activities which receive Federal financial assistance, it does not apply to any age distinction "established under authority of any law" which provides benefits or establishes criteria for participation on the basis of age or in age-related terms. Thus, age, distinctions which are "established under authority of any law" may continue in use. The phrase "any law" means Federal statutes, State statutes or local statutes adopted by elected, general purpose legislative bodies.

The Act excludes from its coverage most employment practices, except for programs funded under the public service employment titles. The regulations cover any program or activity which is both a program of Federal financial assistance and provides employment. The Age Discrimination in Employment Act (ADEA) of 1967, as amended, administered by the Equal Employment Opportunity Commission, prohibits employment discrimination for persons between the ages of 40 and 70. Individuals in this age range who experience employment discrimination, other than in public service employment programs, must look to the ADEA for relief, not to the Age Discrimination Act (ADA). The ADA authorizes a complainant to bring a private lawsuit after the exhaustion of administrative remedies.

The DOC programs of Federal financial assistance are listed in 15 CFR Part 8 Appendix A. The list of programs covered by Title VI of the Civil Rights Act of 1964, 43 FR 49303 (October 23, 1978) and 44 FR 12642 (March 8, 1979) is being revised.

By separate document a new Appendix B will be added to 15 CFR Part 8 reflecting that DOC has no age distinctions which appear in Federal statutes and regulations which affect the agency's programs of Federal financial assistance.

Executive Order 12291

This final rule is not a "major rule" as defined in Executive Order 12291 because it will not result in:

(1) An annual effect on the economy of $100 million or more;

(2) A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or

(3) Significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

The General Counsel of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities because the rule simply establishes basic substantive and procedural elements necessary for the Department to carry out its responsibility under the Age Discrimination Act of 1975. The statutory requirements can be easily integrated into existing nondiscrimination activities and compliance procedures. As a result, neither an initial nor final Regultory Flexibility Analysis has been or will be prepared.

Paper Reduction Act

Under section 3518 of the Paperwork Reduction Act of 1980 and 5 CFR 1320.(c), the information contained in this regulation is not subject to the

Office of Management and Budget review and approval.

List of Subjects in 15 CFR Part 20

Aged; Grants administration.

Katherine M. Bulow,

Assistant Secretary for Administration.

Part 20 is added to Title 15 of the Code of Federal Regulations to read as follows:

PART 20—NONDISCRIMINATION ON THE BASIS OF AGE IN PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

Subpart A—General

Sec.

Subpart B—Standards for Determining Age Discrimination

Subpart C—Responsibilities of DOC Recipients

Subpart D—Investigation, Conciliation, and Enforcement Procedures

Authority: Age Discrimination Act of 1975, as amended, 42 U.S.C. Sec. 6101 *et seq.* and the government-wide regulations implementing the Act, 45 CFR Part 90.

Subpart A—General

§ 20.1 The purpose of DOC's age discrimination regulations.

The purpose of these regulations is to set out DOC's policies and procedures under the Age Discrimination Act of 1975 and the general age discrimination regulations at 45 CFR Part 90. The Act and the general regulations prohibit discrimination on the basis of age in programs or activities receiving Federal financial assistance. The Act and the general regulations permit federally assisted programs and activities, and recipients of Federal funds, to continue to use age distinctions and factors other than age which meet the requirements of the Act and its implementing regulations.

§ 20.2 Programs to which these regulations apply.

(a) The Act and these regulations apply to each DOC recipient and to each program or activity operated by the recipient which receives or benefits from Federal financial assistance provided by any entity of DOC.

(b) The Act and these regulations do not apply to:

(1) An age distinction contained in that part of a Federal, State, or local statute or ordinance adopted by an elected, general purpose legislative body which:

(i) Provides benefits or assistance to persons based on age; or

(ii) Establishes criteria for participation in age-related terms; or

(iii) Describes intended beneficiaries or target groups in age-related terms.

(2) Any employment practice or any employer, employment agency, labor organization, or any labor-management joint apprenticeship training program, except for any program or activity receiving Federal financial assistance for public service employment.

§ 20.3 Definitions.

As used in these regulations, the following terms are defined as follows:

(a) "Act" means the Age Discrimination Act of 1975, as amended (Title III of Pub. L. 94–135).

(b) "Action" means any act, activity, policy, rule, standard, or method of administration; or the use of any policy, rule, standard, or method of administration.

(c) "Age" means how old a person is, or the number of years from the date of a person's birth.

(d) "Age distinction" means any action using age or an age-related term.

(e) "Age-related term" means a word or words which necessarily imply a particular age or range of ages (for example: "children," "adult," "older persons," but not "student").

(f) "Agency" means a Federal department or agency that is empowered to extend financial assistance.

(g) "DOC" means the U.S. Department of Commerce.

(h) "Federal financial assistance" means any grant, entitlement, loan, cooperative agreement, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the agency provides or otherwise makes available assistance in the form of:

(1) Funds; or

(2) Services of Federal personnel; or

(3) Real and personal property or any interest in or use of property, including:

(i) Transfers or leases of property for less than fair market value or for reduced considerations; and

(ii) Proceeds from a subsequent transfer or lease of property if the Federal share of its fair market value is not returned to the Federal Government.

(i) "Normal operation" means the operation of a program or activity without significant changes that would impair its ability to meet its objectives.

(j) "Recipient" means any State or its political subdivision, any instrumentality of a State or its political sub-division, any public or private agency, institution, organization, or other entity, or any person to which Federal financial assistance is extended, directly or through another recipient. Recipient includes any successor, assignee, or transferee, but excludes the ultimate beneficiary of the assistance.

(k) "Secretary" means the Secretary of Commerce or his or her designee.

(l) "Statutory objective" means any purpose of a program or activity expressly stated in any Federal statute, State statute, or local statute or ordinance adopted by an elected, general purpose legislative body.

(m) "Subrecipient" means any of the entities in the definition of "recipient" to which a recipient extends or passes on Federal financial assistance. A subrecipient is generally regarded as a recipient of Federal financial assistance and has all the duties of a recipient in these regulations.

(n) "United States" means the fifty States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, Wake Island, the Canal Zone, the Northern Marianas, and the territories and possessions of the United States.

Subpart B—Standards for Determining Age Discrimination

§ 20.4 Rules against age discrimination.

The rules stated in this section are limited by the exceptions contained in § 20.5.

(a) General rule: No person in the United States shall, on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.

(b) Specific rules: A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual licensing, or other arrangements, use age distinctions or

take any other actions which have the effect, on the basis of age, of:

(1) Excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance, or

(2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.

(c) The specific forms of age discrimination listed in paragaph (b) of this section do not necessarily constitute a complete list.

(d) If a recipient operating a program provides special benefits to the elderly or to children, such use of age distinctions shall be presumed to be necessary to the normal operation of the program, notwithstanding the provisions of § 20.5.

§ 20.5 Exceptions to the rules.

(a) *Normal operations or statutory objective of any program or activity.* A recipient is permitted to take an action otherwise prohibited by § 20.4 if the action reasonably considers age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity. An action meets this standard if:

(1) Age is used as a measure or approximation of one or more other characteristics; and

(2) The other characteristic(s) must be measured or approximated in order for the normal operation of the program or activity to continue, or to achieve any statutory objective or the program or activity; and

(3) The other characteristic(s) can be reasonably measured or approximated by the use of age; and

(4) The other characteristic(s) are impractical to measure directly on an individual bases.

(b) *Reasonable factors other than age.* A recipient is permitted to take an action otherwise prohibited by § 20.4 which is based on a factor other than age, even though that action may have a disproportionate effect on persons of different ages. An action may be based on a factor other than age only if the factor bears a direct and substantial relationship to the normal operation of the program or activity or to the achievement of a statutory objective.

§ 20.6 Burden of proof.

The burden of proving that an age distinction or other action falls within the exceptions outlined in § 20.5 is on the recipient of Federal financial assistance.

Subpart C—Responsibilities of DOC Recipients

§ 20.7 General responsibilities.

Each DOC recipient has primary responsibility to ensure that its programs and activities are in compliance with the Act, the general regulations, and these regulations, and shall take steps to eliminate violation of the Act.

(a) Each DOC recipient will provide an assurance that the program for which it is receiving Federal financial assistance will be conducted in compliance with all requirements for the Act and these and other DOC regulations. A recipient also has responsibility to maintain records, provide information, and to afford DOC reasonable access to its records and facilities to the extent necessary to determine whether it is in compliance with the Act and these regulations.

(b) *Recipient assessment of age distinctions.* (1) To assess the recipient's compliance with the Act, DOC may, as part of a compliance review under § 20.10 or a complaint investigation under § 20.11, require a recipient employing the equivalent or 15 or more employees, to complete, in a manner specified by the responsible Department official, a written self-evaluation of any age distinction imposed in its program or activity receiving Federal financial assistance from DOC.

(2) Whenever an assessment indicates a violation of the Act and the DOC regulations, the recipient shall take corrective action.

§ 20.8 Notice of subrecipients

Where a recipient passes on Federal financial assistant from DOC to subrecipients, the recipient shall give subrecipients written notice of their obligations under the Act and these regulations.

§ 20.9 Information requirements

Upon DOC's request, each recipient shall provide access and make information available for DOC to determine whether the recipient is complying with the Act and these regulations.

Subpart D—Investigation, Conciliation, and Enforcement Procedures

§ 20.10 Compliance reviews.

(a) DOC may conduct compliance reviews and pre-award reviews or use other similar procedures that will permit it to investigate and correct violations of the Act and these regulations. DOC may conduct such review even in the absence of a complaint against a recipient. The review may be as comprehensive as necessary to determine whether a violation of the Act and these regulations has occurred.

(b) If a compliance review of pre-award review indicates a violation of the Act or these regulations, DOC will attempt to achieve voluntary compliance with the Act. If voluntary compliance cannot be achieved, DOC will arrange for enforcement as described in § 20.15.

§ 20.11 Complaints.

(a) Any person, individually, or as a member of a class, or on behalf of others, may file a complaint with DOC alleging discrimination prohibited by the Act or these regulations based on an action occurring on or after July 1, 1979. A complainant shall file a complaint within 180 days from the date the complainant first had knowledge of the alleged act of discrimination. However, for good cause shown, DOC may extend this time limit.

(b) DOC will attempt to facilitate the filing of complaints wherever possible, including taking the following measures:

(1) Accepting as a sufficient complaint, any written statement which: identifies the parties involved and the date the complainant first had knowledge of the alleged violation; describes generally the action or practice complained of; and is signed by the complainant;

(2) Freely permitting a complainant to add information to the complaint to meet the requirements of a sufficient complaint;

(3) Considering as the filing date, the date on which a complaint is sufficient to be processed;

(4) Notifiying the complainant and the recipient of their rights and obligations under the compliant procedure, including the right to have a representative at all stages of the process;

(5) Notifying the complainant and the recipient (or their representatives) of their right to contact DOC for information and assistance regarding the complaint resolution process.

(c) DOC will return to the complainant any complaint outside the jurisdiction of these regulations, and will state the reason(s) why it is outside the jurisdiction of these regulations.

§ 20.12 Mediation.

(a) DOC will refer to a mediation service designated by the Secretary all sufficient complaints that:

(1) Fall within the jurisdiction of the Act and these regulations, unless the age distinction complained of is clearly within an exception; and

(2) Contain all information necessary for further processing.

(b) Both the complainant and the recipient shall participate in the mediation process to the extent necessary to reach an agreement or to make an informed judgment that an agreement is not possible.

(c) If the complainant and the recipient reach an agreement, the mediator shall prepare a written statement of the agreement and have the complainant and the recipient sign it. The mediator shall send a copy of the agreement to DOC. DOC will take no further action on the complaint unless the complainant or the recipient fails to comply with the agreement.

(d) The mediator is required to protect the confidentiality of all information obtained in the course of the mediation process. No mediator shall testify in any adjudicative proceeding, produce any document, or otherwise disclose any information obtained, in the course of the mediation process without prior approval of the head or the mediation service.

(e) The mediation will proceed for a maximum of 60 days after a complaint is filed with DOC. Mediation ends if:

(1) 60 days elapse from the time DOC receives the complaint; *or*

(2) Prior to the end of that 60-day period, an agreement is reached; *or*

(3) Prior to the end of that 60-day period, the mediator determines that an agreement cannot be reached.

(f) The mediator shall return unresolved complaints to DOC.

§ 20.13 Investigation.

(a) Informal investigation:

(1) DOC will investigate complaints that are unresolved after mediatioin or are reopended because of a violation of a mediation agreement.

(2) As part of the initial investigation, DOC will use informal factfinding methods, including joint or separate discussions with the complainant and recipient, to establish the facts and, if possible, settle the complaint on terms that are mutually agreeable to the parties. DOC may seek the assistance of any involved State program agency.

(3) DOC will put any agreement in writing and have it signed by the parties and an authorized offical at DOC.

(4) The settlement shall not affect the operation of any other enforcement effort of DOC, including compliance reviews and investigation or other complaints which may involve the recipient.

(5) The settlement is not a finding of discrimination against a recipient.

(b) Formal investigation: If DOC cannot resolve the complaint through informal investigation, it will begin to develop formal findings through further investigation of the complaint. If the investigation indicates a violation of these regulations, DOC will attempt to obtain voluntary compliance. If DOC cannot obtain voluntary compliance, it will begin enforcement as described in § 8a.15.

§ 20.14 Prohibition against intimidation or retaliation.

A recipient may not engage in acts of intimidation or retaliation against any person who:

(a) Attempts to assert a right protected by the Act or these regulations; or

(b) Cooperates in any mediation, investigation, hearing, or other part of DOC's investigation, conciliation, and enforcement process.

§ 20.15 Compliance procedure.

(a) DOC may enforce the Act and these regulations by:

(1) Terminating the Federal financial assistance to the recipient under the program or activity found to have violated the Act or these regulations. The determination of the recipient's violation may be made only after a recipient has had an opportunity for a hearing on the record before an administrative law judge. If a case is settled during mediation, or prior to hearing, Federal financial assistance to the program will not be terminated.

(2) Any other means authorized by law including but not limited to:

(i) Referral to the Department of Justice for proceedings to enforce any rights of the United States or obligations of the recipient created by the Act or these regulations.

(ii) Use of any requirement of or referral to any Federal, State, or local government agency that will have the effect of correcting a violation of the Act or these regulations.

(b) DOC will limit any termination under this section to the particular recipient and particular program or activity or part of such program and activity DOC finds in violation of these regulations. DOC will not base any part of a termination on a finding with respect to any program or activity of the recipient which does not receive Federal financial assistance from DOC.

(c) DOC will take no action under paragraph (a) until:

(1) The head of the organization providing the financial assistance has advised the recipient of its failure to comply with the Act and these regulations and has determined that voluntary compliance cannot be obtained.

(2) Thirty days have elapsed after the Secretary has sent a written report of the circumstances and grounds of the action to the committees of the Congress having legislative jurisdiction over the Federal program or activity involved. The Secretary will file a report whenever any action is taken under paragraph (a).

(d) DOC also may defer granting new Federal financial assistance to a recipient when a hearing under § 20.16 is initiated.

(1) New Federal financial assistance from DOC includes all assistance for which DOC requires an application or approval, including renewal or continuation of existing activities, or authorization of new activities, during the deferral period. New Federal financial assistance from DOC does not include increases in funding as a result of changed computation of formula awards or assistance approved prior to the beginning of a hearing under § 20.16.

(2) DOC will not begin a deferral until the recipient has received a notice of an opportunity for a hearing under § 20.16. DOC will not continue a deferral for more than 60 days unless a hearing has begun within that time, or the time for beginning the hearing has been extended by mutual consent of the recipient and the head of the organization providing Federal financial assistance. DOC will not continue a deferral for more than 30 days after the close of the hearing, unless the hearing results in a finding against the recipient.

(3) DOC will limit any deferral to the particular recipient and particular program or activity or part of such program or activity DOC finds in violation of these regulations. DOC will not base any part of a deferral on a finding with respect to any program or activity of the recipient which does not, and would not in connection with the new funds, receive Federal financial assistance for DOC.

§ 20.16 Hearings, decisions, post-termination proceedings.

Certain DOC procedural provisions applicable to Title VI of the Civil Rights Act of 1964 apply to DOC enforcement of these regulations. They are found in 15 CFR Part 8, § 8.12 and § 8.13.

§ 20.17 Remedial action by recipients.

(a) Where DOC finds that a recipient has discriminated on the basis of age, the recipient shall take any remedial action that DOC may require to overcome the effects of the discrimination. If another recipient exercises control over the recipient that

has discriminated, DOC may require both recipients to take remedial action.

(b) Even in the absence of a finding of discrimination, a recipient may take affirmative action to overcome the effects of conditions that resulted in limited participation in the recipient's program or activity on the basis of age.

§ 20.18 Alternative funds disbursal procedure.

(a) When, under the provisions of these regulations, DOC terminates the funding of a recipient, the Secretary may, using undisbursed funds from the terminated award, make a new award to an alternate recipient, *i.e.* any public or non-profit private organization or agency, or State or political subdivision of the State.

(b) The Secretary will require any alternate recipient to demonstrate:

(1) The ability to comply with these regulations; and

(2) The ability to achieve the goals of the Federal statute authorizing the program or activity.

§ 20.19 Private lawsuits after exhaustion of administrative remedies.

(a) A complainant may file a civil action following the exhuastion of administrative remedies under the Act. Administrative remedies are exhausted if:

(1) 180 days have elapsed since the complainant filed the complaint and DOC has made no finding with regard to the complaint; or

(2) DOC issues any finding in favor of the recipient.

(b) If DOC fails to make a finding within 180 days or issues a finding in favor of recipient, DOC shall:

(1) Promptly advise the complainant of this fact; and

(2) Advise the complainant of his or her right to bring civil action for injunctive relief; and

(3) Inform the complainant that:

(i) The complainant may bring a civil action only in a United States district court for the district in which the recipient is located or transacts business;

(ii) A complainant prevailing in a civil action has the right to be awarded the costs of the action, including reasonable attorney's fees, but that the complainant must demand these costs in the complaint;

(iii) Before commencing the action, the complainant shall give 30 days notice by registered mail to the Secretary, the Attorney General of the United States, and the recipient;

(iv) The notice shall contain the alleged violation of the Act, the relief requested, the court in which the complainant is bringing the action, and whether or not attorney's fees are demanded in the event the complainant prevails; and

(v) The complainant may not bring an action if the same alleged violation of the Act by the same recipient is the subject of a pending action in any court of the United States.

[FR Doc. 86-18156 Filed 8-12-86; 8:45 am]
BILLING CODE 3510-BP-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. 86N-0282; Formerly Docket No. 83C-0130]

[Phthalocyaninato(2-)] Copper; Migration from Nonabsorbable Sutures

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the color additive regulations by removing the provision that prohibits the migration of [phthalocyaninato(2-)] copper from nonabsorbable sutures to the surrounding tissues when the sutures are used for the purposes specified in their labeling. FDA is taking this action based on a proposal published previously in the **Federal Register**. The proposal made clear that the restriction is impractical and unnecessary to assure the safety or suitability of the use of [phthalocyaninato(2-)] copper in coloring nonabsorbable sutures.

DATES: Effective September 15, 1986, except as to any provisions that may be stayed by the filing of proper objections; objections by September 12, 1986. FDA will publish notice of the objections received or lack thereof in the **Federal Register**.

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

FOR FURTHER INFORMATION CONTACT: Marvin D. Mack, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 25, 1985 (50 FR 16310), FDA proposed that 21 CFR Part 74 be amended in § 74.3045 (21 CFR 74.3045) by removing paragraph (c)(1)(iii). As explained in the proposal, paragraph (c)(1)(iii) contains the provision that prohibits the migration of [phthalocyaninato(2-)] copper from a suture to surrounding tissues under the conditions of use. FDA is taking this action because, as explained in the proposal, the restriction is not necessary to assure the safety or suitability of the use of [phthalocyaninato(2-)] copper in sutures.

In the proposed rule, FDA gave interested persons until June 24, 1985, to file comments. The agency did not receive any comments on the proposed rule. Therefore, FDA is publishing the final rule without change.

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (April 25, 1985; 50 FR 16310). 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.

In accordance with the Regulatory Flexibility Act, the agency previously considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined that no significant impact on a substantial number of small entities would derive from this action. FDA has not received any new information or comments that would alter its previous determination.

Any person who will be adversely affected by this regulation may at any time on or before September 12, 1986 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. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register.**

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 74 is amended as follows:

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

1. The authority citation for 21 CFR Part 74 continues to read as follows:

Authority: Secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376); 21 CFR 5.10.

§ 74.3045 [Amended]

2. Section 74.3045 [*Phthalocyaninato(2-)*] copper is amended by removing paragraph (c)(1)(iii).

Dated: August 6, 1986.

John M. Taylor,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 86–18218 Filed 8–8–86; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 178

[Docket No. 84F-0170]

Indirect Food Additives: 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 a mixture of reaction products, produced by reacting octadecylamine with ethylene oxide and further reacting this product with octadecanoic acid, as an antistatic agent for polypropylene film. This action responds to a petition filed by Matsumoto Yushi-Seiyaku Co., Ltd.

DATES: Effective August 13, 1986; objections by September 12, 1986. The Director of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 178.3130 effective August 13, 1986.

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: Vir Anand, Center for Food Safety and Applied Nutrition (HFF–335), 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 June 14, 1984 (49 FR 24601), FDA announced that a petition (FAP 4B3801) has been filed by Matsumoto Yushi-Seiyaku Co., Ltd., c/o Center for Regulatory Services, 2347 Paddock Lane, Reston, VA 22091, proposing that § 178.3130 (21 CFR 178.3130) be amended to provide for the safe use of ethoxylated octadecylamine (ethylene oxide reacted with octadecylamine) reacted with octadecanoic acid as an antistatic agent in polypropylene films complying with 21 CFR 177.1520.

FDA, in its evaluation of the safety of this additive, reviewed the safety of both the additive and the starting materials used to manufacture the additive. Although ethoxylated octadecylamine reacted with octadecanoic acid has not been found to cause cancer, it may contain mimute amounts of ethylene oxide and 1,4-dioxane as byproducts of its production. These chemicals have been shown to cause cancer in test animals. Residual amounts of reactants and manufacturing aids, such as these chemicals, are commonly found as contaminants in chemical products, including food additives.

I. Determination of Safety

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 a fair evaluation of the data available to FDA establishes that the additive is safe for that use. The concept of safety embodied in the Food Additives Amendment of 1958 is explained in the legislative history of the 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 circumstance." H. Rept. 2284, 85th Cong., 2d Sess. 4 (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 Additive 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 often refused to approve the use of an additive that contained or was suspected of containing even minor amounts of a carcinogenic chemical, even though 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 to establish the safety of additives that contain carcinogenic chemicals but that have not themselves been shown to cause cancer.

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 explained the basis for approving 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 other color additives and food additives on the same basis. FDA fully explained the scientific, legal, and policy underpinnings for these decisions in the advance notice of proposed rulemaking on a policy for regulating carcinogenic chemicals in food and color additives, published in the **Federal Register** of April 2, 1982 (47 FR 14464).

The agency now believes that the Delaney or anticancer clause is applicable only when 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 evaluated 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.

The agency's position is supported by *Scott* v. *FDA*, 728 F.2d 322 (6th Cir. 1984). That case involved a challenge to FDA's decision to approve the use of D&C Green No. 5, which contains a carcinogenic chemical but has itself not been shown to cause cancer. Relying heavily on the reasoning in the agency's decision to list this color additive, the United States Court of Appeals for the Sixth Circuit rejected the challenge to FDA's action and affirmed the listing regulation.

II. Safety of Petitioned Use

FDA estimates that the petitioned use of ethoxylated octadecylamine reacted