* * * * *

(b) Statements. (1) Except as provided in paragraph (c) of this section, any person who makes a written statement that—* * *

(ii) Contains, or is accompanied by, an express certification or affirmation of the truthfulness and accuracy of the contents of the statement, shall be subject, in addition to any other remedy that may be prescribed by law, to a civil penalty of not more than $5,500.[2]

* * * * *

Issued this 3rd day of February, 1997, at Washington, D.C.

Federico Peña,

Secretary of Transportation.

[FR Doc. 97–3238 Filed 2–12–97; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

[T. D. 97–7]

Establishment of Port of Entry at Spirit of St. Louis Airport

AGENCY: Customs Service, Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations pertaining to the field organization of Customs by designating a port of entry at the Spirit of St. Louis Airport in St. Louis County, Missouri. This designation is pursuant to Congressional direction in Public Law 104–208.

EFFECTIVE DATE: March 17, 1997.

FOR FURTHER INFORMATION CONTACT: Harry Denning, Office of Field Operations, (202) 927–0196.

SUPPLEMENTARY INFORMATION:

Background

As part of a continuing program to obtain more efficient use of its personnel, facilities, and resources, and to provide better service to carriers, importers, and to the general public, Customs is amending § 101.3, Customs Regulations (19 CFR 101.3), by designating a port of entry at the Spirit of St. Louis Airport in St. Louis County, Missouri. This designation is pursuant to Congressional direction in Public Law 104–208 of September 30, 1996.

[2] As adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101–140), as amended by the Debt Collection Improvement Act of 1996 (Pub. L. 104–143, section 31001).

Port Limits

The port limits of the Spirit of St. Louis Airport encompass the following territory:

A tract of land in the City of Chesterfield, St. Louis County, Missouri, described as follows: The point of beginning located at the intersection of the Missouri River Interstate 64/U.S. Highway 40/61 Bridge and the Monarch-Chesterfield Levee; thence eastwardly along said Levee to Bonhomme Creek; thence southwestwardly along said Levee across its eastern intersection with Interstate 64 and its intersection with Chesterfield Airport Road to its connection with the St. Louis Southwestern Railroad rail bed just east of Long Road; thence westwardly along said Railroad right-of-way to its intersection with Eatherton Road; thence northwardly along Eatherton Road to a point where it intersects with Olive Street Road and the Levee; thence northeastwardly along said Levee to the point of beginning.

Regulatory Flexibility Act and Executive Order 12866

Because this document relates to agency management and organization and because this amendment is directed by Congress, this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553. Accordingly this document is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

This document does not meet the criteria for a significant regulatory action under Executive Order 12866.

Inapplicability of Public Notice and Comment Requirements

Inasmuch as this amendment is the direct result of Congressional direction, pursuant to 5 U.S.C. 553(a)(2) and (b)(B), good cause exists for dispensing with the notice and public procedure thereon as unnecessary.

Drafting Information

The principal author of this document was Janet Johnson, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Organization and functions (Government agencies).

Amendments to the Regulations

For the reasons set forth in the preamble, part 101 of the Customs Regulations is amended as set forth below.

PART 101—GENERAL PROVISIONS

1. The general authority citation for Part 101 and the specific authority for § 101.3 continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 2, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1623, 1624. Sections 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

* * * * *

§ 101.3 [Amended]

2. Section 101.3(b)(1) is amended by adding, in alphabetical order under the state of Missouri, ''Spirit of St. Louis Airport'' in the ''Ports of entry'' column and, adjacent to this entry, ''Including territory described in T. D. 97–7'' in the ''Limits of port'' column.

Approved: January 17, 1997.

George J. Weise,

Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 97–3619 Filed 2–12–97; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 89F–0331]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

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 2,3,4,5-tetrachloro-6-cyanobenzoic acid, methyl ester reaction products with *p*-phenylenediamine and sodium methoxide as a colorant in all food-contact polymers. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective February 13, 1997; written objections and requests for a hearing by March 17, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard H. White, Center for Food

Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3094.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of August 29, 1989 (54 FR 35725), FDA announced that a food additive petition (FAP 9B4158) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188 (currently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of 2,3,4,5-tetrachloro-6-cyanobenzoic acid, methyl ester reaction products with *p*-phenylenediamine and sodium methoxide as a colorant in all food-contact polymers.

In its evaluation of the safety of this food additive, FDA reviewed the safety of the additive 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 polychlorinated biphenyls (PCB's), which are carcinogenic impurities resulting from manufacture of the additive. Residual amounts of reactants, manufacturing aids and their constituent impurities and by-products, such as PCB's, 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 to be safe if it is found to induce cancer when ingested by man or animal. Importantly, however, the Delaney clause applies to the food additive itself and not to the 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 clause using risk assessment procedures to determine whether there is a reasonable certainty that no harm will result from the proposed use of the food 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 food additive, 2,3,4,5-tetrachloro-6-cyanobenzoic acid, methyl ester reaction products with *p*-phenylenediamine and sodium methoxide, will result in exposure to no greater than 1.3 parts per billion (ppb) of the additive in the daily diet (3 kilograms (kg)), or an estimated dietary intake (EDI) of 3.9 micrograms per person per day (μg/person/day) (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 (acute toxicity and mutagenicity studies) on the additive and concludes that the small dietary exposure resulting from the proposed use of the additive is safe.

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

A. PCB's

FDA has estimated the hypothetical worst-case exposure to PCB's from the petitioned use of the food additive as a colorant in polymers to be less than 0.32 parts per quadrillion of the daily diet (3 kg), or 0.96 picogram per person per day (pg/person/day) (Ref. 3). The agency used data from a carcinogenesis bioassay on PCB's, conducted by Norback and Weltman (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to these chemicals resulting from the proposed use of the food additive (Ref. 5). The results of the bioassay on a PCB mixture (Aroclor 1260) demonstrated that the material was carcinogenic for male and female rats under the conditions of the study. The test material caused significantly increased incidence of hepatocellular tumors in both female and male rats.

Based on the estimated worst-case exposure to PCB's of 0.96 pg/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the use of the subject additive is less than 9×10^{-12} or 9 in 1 trillion (Refs. 6 and 7). Because of the numerous conservative assumptions used are in calculating the exposure estimate, the actual lifetime-averaged individual exposure to PCB's is likely to be substantially less than the potential worst-case exposure, and therefore, the upper-bound limit of lifetime human risk would be less. Thus, the agency concludes that there is a reasonable certainty that no harm from exposure to PCB's would result from the proposed use of the additive.

B. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of PCB's present as impurities in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low levels at which PCB's may be expected to remain as impurities following production of the additive, the agency would not expect these impurities to become components of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to these impurities, even under worst-case assumptions, is very low, less than 9 in 1 trillion.

III. Conclusion on Safety

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 food additive as a colorant in polymers in contact with food is safe, that the food additive will achieve its intended technical effect and that the regulations in § 178.3297 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 carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a 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 that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before March 17, 1997, 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.

VI. 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 dated November 1, 1989, from the Food and Color Additives Review Section (HFF–415) to Indirect Additives Branch (HFF–335) concerning ''FAP 9B4158—Ciba-Geigy Corp. Submission dated 7–7–89. Irgazin Yellow 3RLTN as a colorant in polymeric food packaging.''

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

3. Memorandum dated May 23, 1995, from the Chemistry Review Branch (HFS–247) to Indirect Additives Branch (HFS–216).

4. Norback, D. H., and R. H. Weltman., ''Polychlorinated Biphenyl Induction of Hepatocellular Carcinoma in the Sprague-Dawley Rat,'' *Environmental Health Perspectives,* 60:97–105, 1985.

5. Gaylor, D. W., and R. L. Kodell., ''Linear Interpolation Algorithm for Low Dose Risk Assessment of Toxic Substances,'' *Journal of Environmental Pathology and Toxicology,* 4:305–312, 1980.

6. Memorandum, Report of the Quantitative Risk Assessment Committee, August 18, 1995.

7. Memorandum dated October 11, 1996, from the Quantitative Risk Assessment Committee (HFS–16) to Indirect Additives Branch (HFS–216) concerning ''Clarification of QRAC Memorandum of August 18, 1995, re FAPs 9B4158 and 3B4349.''

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: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3297 is amended in the table in paragraph (e) by alphabetically adding a new entry under the headings ''Substances'' and ''Limitations'' to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
2,3,4,5-Tetrachloro-6-cyanobenzoic acid, methyl ester reaction products with *p*-phenylenediamine and sodium methoxide (CAS Reg. No. 106276–80–6)	For use only at levels not to exceed 1 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through H, described in Table 2, of § 176.170(c) of this chapter.
* * *	* * * *

Dated: February 5, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–3661 Filed 2–12–97; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) from Biocraft Laboratories, Inc., to Teva Pharmaceuticals USA.

EFFECTIVE DATE: February 13, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Biocraft Laboratories, Inc., 92 Route 46, Elmwood Park, NJ 07407, has informed FDA that it has transferred ownership of, and all rights and interests in NADA 131–806 for furosemide tablets or boluses to Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by alphabetically adding a new listing for Teva Pharmaceuticals USA. The agency is also amending 21 CFR 520.1010a to reflect the transfer of ownership.