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.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Teva Pharmaceuticals USA'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''000093'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960	000093
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
000093	Teva Pharmaceuticals USA, 650 Cathill Rd., Sellersville, PA 18960
* * *	* * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.1010a [Amended]

4. Section 520.1010a *Furosemide tablets or boluses* is amended in paragraph (b) by removing the number ''000332'' and adding in its place ''000093''.

Dated: February 4, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–3662 Filed 2–12–97; 8:45 am]

BILLING CODE 4160–01–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[TN–155–1–7178; TN–MEM–149–3–9701; FRL–5669–3]

Approval and Promulgation of Implementation Plans; State of Tennessee and Memphis-Shelby County, Tennessee

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving revisions to the Tennessee State Implementation Plan (SIP) to allow the State to issue Federally enforceable state operating permits (FESOP). EPA is also approving revisions to the Memphis-Shelby County portion of the Tennessee SIP to allow the County to issue Federally enforceable local operating permits (FELOP). EPA is also approving the State's FESOP program and the County's FELOP program pursuant to section 112 of the Clean Air Act as amended in 1990 (CAA or ''the Act'') so that both permitting agencies may issue Federally enforceable state operating permits containing limits for hazardous air pollutants (HAP).

DATES: This final rule is effective April 14, 1997 unless adverse or critical comments are received by March 17, 1997. If the effective date is delayed, timely notice will be published in the Federal Register.

ADDRESSES: Written comments should be addressed to Gracy R. Danois at the EPA Regional Office listed below. Copies of the documents used in developing this action are available for public inspection during normal business hours at the locations listed below. Interested persons wanting to examine these documents, contained in files TN155 and TN149–3, should make an appointment with the appropriate office at least 24 hours before the visiting day:

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

U.S. Environmental Protection Agency, Region 4, Air and Radiation Technology Branch, Atlanta Federal