(''PRA''):[17] Reports to be Made by Certain Brokers and Dealers; Rule 17a–5(e)(5)—Year 2000 Problem.[18] Accordingly, the amendment to the collection of information requirement regarding the accountant's report was submitted to the Office of Management and Budget (''OMB'') for review and was approved by OMB which assigned the following control number 3235–0511.

The Proposing Release solicited comments on the proposed collection of information. No comments were received that specifically addressed the PRA submission. However, as discussed in sections III. and IV. above, the Commission received suggestions that would improve the reporting requirement. Based upon these suggestions, the collection of information has been adjusted as described in section III. above and is in accordance with Section 3507 of the PRA.[19] These adjustments include reducing the scope of accountant's review to increase the consistency, accuracy and comparability of the information collected. In addition, the adjustments will reduce the time required to summarize, track, analyze, and report the information received.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the agency displays a valid OMB control number. Broker-dealers are required to comply with the collection of information pursuant to the amendments to Rule 17a–5 and the information is necessary to provide the Commission with a better understanding of the security industry's readiness for the Year 2000. The information collected pursuant to the amendments to Rule 17a–5 will be public.

As previously discussed, the Commission has reduced the scope of the independent public accountant's review. However, after carefully considering the comments received, the Commission is retaining its original estimate of the burden hours associated with obtaining the independent public accountant's report. Thus, the Commission estimates that under the final amendments, a broker-dealer will, on average, spend 20 hours obtaining the independent public accountant's report. This is in addition to the two hours a broker-dealer will spend preparing Part I of Form BD–Y2K and for those broker-dealers with a minimum net capital requirement of $100,000 or greater, the 35 hours they will spend preparing Part II of Form BD–Y2K.

The total annualized burden to the securities industry is estimated to be 146,750 hours. This is based on approximately 6,000 respondents spending on average two hours completing Part I of Form BD–Y2K; approximately 2,450 respondents spending on average 35 hours preparing Part II of Form BD–Y2K and an additional 20 hours working with their independent public accountant on the independent public accountant's report.

VIII. Statutory Basis

Pursuant to the Securities Exchange Act of 1934 and particularly sections 17(a) and 23(a) thereof, 15 U.S.C. 78o(c)(3) and 78w, the Commission is adopting amendments to § 240.17a–5 of Title 17 of the Code of Federal Regulations in the manner set forth below.

List of Subjects in 17 CFR Part 240 and 249

Broker-dealers, Reporting and recordkeeping requirements, Securities.

Text of Final Rule

In accordance with the foregoing, Title 17, chapter II, part 240 of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

1. The authority citation for part 240 continues to read in part as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78d, 78f, 78i, 78j, 78j–1, 78k, 78k–1, 78*l*, 78m, 78n, 78o, 78p, 78q, 78s, 78u–5, 78w, 78x, 78*ll*(d), 78mm, 79q, 79t, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4 and 80b–11, unless otherwise noted.

* * * * *

2. By amending § 240.17a–5 by adding paragraph (e)(5)(vi) to read as follows:

§ 240.17a–5 Reports to be made by certain brokers and dealers.

* * * * *

(e) *Nature and form of reports.* * * *

(5) * * *

(vi) No later than April 30, 1999, every broker or dealer required to file Part II of Form BD–Y2K (§ 249.618 of this chapter) pursuant to paragraph (e)(5)(iii)(B) of this section and required to file audited financial statements pursuant to paragraph (d) of this section shall file with its Form BD–Y2K an original and two copies of a report prepared by an independent public accountant regarding the broker's or dealer's process, as of March 15, 1999, for addressing Year 2000 Problems with the Commission's principal office in Washington, DC and one copy of the accountant's report with the designated examining authority of the broker or dealer. The independent public accountant's report shall be prepared in accordance with standards that have been reviewed by the Commission and that have been issued by a national organization that is responsible for promulgating authoritative accounting and auditing standards.

* * * * *

Dated: October 28, 1998.

By the Commission.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–29343 Filed 11–2–98; 8:45 am]

BILLING CODE 8010–01–U

[17] 44 U.S.C. 3501 *et seq.*

[18] The Office of Management and Budget (''OMB'') control number is 3235/0511.

[19] 44 U.S.C. 3507

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F–0214]

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 2,9-dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione (C.I. Pigment Red 202) as a colorant for polymers used in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: The regulation is effective November 3, 1998; submit written objections and requests for a hearing December 3, 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 July 5, 1996 (61 FR 35229), FDA announced that a food additive petition (FAP 6B4512) had been filed by Ciba-Geigy Corp., 335 Water St., Newport, DE

19804 (currently, 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 § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of 2,9-dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione (C.I. Pigment Red 202) as a colorant in polymers used 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 *para*-chloroaniline, a carcinogenic impurity resulting from the manufacture of the additive. Residual amounts of reactants and manufacturing aids, such as *para*-chloroaniline, 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 additive anticancer, or Delaney, clause of the act further 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 constituents of 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, 2,9-dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione, will result in exposure to no greater than 2.5 parts per billion of the additive in the daily diet (3 kilogram (kg)), or an estimated daily intake of 7.5 microgram per person per 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 on the additive and concludes that the estimated small dietary exposure resulting from the proposed use of this 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 *para*-chloroaniline, the carcinogenic chemical that may be present as an impurity in the additive. The risk evaluation of *para*-chloroaniline has two aspects: (1) Assessment of exposure to the impurity from the proposed use of the additive; and (2) extrapolation of the risk observed in the animal bioassay to the conditions of probable exposure to humans.

A. Para-Chloroaniline

FDA has estimated the exposure to *para*-chloroaniline from the petitioned use of the additive as a colorant in polymers to be 20 parts per trillion in the daily diet (3 kg), or 60 nanograms per person per day (ng/p/d) (Ref. 1). The agency used data from a carcinogenicity study of *para*-chloroaniline conducted by the National Toxicology Program (NTP) (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 NTP carcinogenicity studies on this chemical demonstrated that administration of the test material to Fisher 344 rats by gavage caused increased incidence of splenic sarcomas in male rats.

Based on the agency's estimated exposure to *para*-chloroaniline of 60 ng/p/d, FDA estimates that the upper-bound limit of lifetime human risk from the proposed use of the subject additive is 1×10^{-8}, or 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 *para*-chloroaniline 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 *para*-chloroaniline 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 *para*-chloroaniline present as an impurity in the additive. The agency finds that specifications are not necessary for the following reasons: (1) Because of the low level at which *para*-chloroaniline may be expected to remain as an impurity following production of the additive, the agency would not expect the impurity to become a component of food at other than extremely low levels; and (2) the upper-bound limit of lifetime human risk from exposure to the impurity is very low, less than 1 in 100 million.

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 as a colorant in polymers in contact with food is safe, and that the additive will achieve its intended technical effect. Therefore, the agency concludes 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 (address above) 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. 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 anytime on or before December 3, 1998, file with the Dockets Management Branch (address above) written objection 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 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 objection 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 dated August 29, 1996, from the Chemistry Review Branch (HFS–247), to the file concerning FAP 6B4512, dietary concentrations of the additive and the impurity (*para*-chloroaniline).

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. Chhabra, R. S., Toxicology and Carcinogenesis Studies of *para*-Chloroaniline Hydrochloride in F344/N Rats and B6C3F1 Mice (Gavage Studies), National Toxicology Program, Technical Report Series No. 351, July 1989.

4. Report of the Quantitative Risk Assessment Committee, FDA, concerning ''Assessment of Carcinogenic upper-bound lifetime risk resulting from contamination by *para*-chloroaniline residues in C.I. Pigment Red 202 (Ciba-Geigy Corp.), FAP 6B4512, dates April 9, 1998.

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

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
2,9-Dichloro-5,12-dihydroquinone[2,3-b]acridine-7,14-dione (C.I. Pigment Red 202, CAS Reg. No. 3089–17–6).	For use at levels not to exceed 1.0 percent by weight of polymers.
* * *	* * * *

Dated: October 26, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–29333 Filed 11–2–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

Implantation or Injectable Dosage Form New Animal Drugs; Hyaluronate Sodium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Anika Therapeutics, Inc. The supplemental NADA provides for equine use of hyaluronate sodium injection containing 11 milligrams hyaluronate sodium per milliliter (mg/mL) rather than the currently approved 10 mg/mL.

EFFECTIVE DATE: November 3, 1998.

FOR FURTHER INFORMATION CONTACT: Dennis M. Bensley, Jr., Center For Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–4105.

SUPPLEMENTARY INFORMATION: Anika Therapeutics, Inc., 236 West Cummings Park, Woburn, MA 01810, formerly Anika Research, Inc., 160 New Boston St., Woburn, MA 01801, filed supplemental NADA 122–578 that provides for equine use of a 11-mg/mL Hyvisc (hyaluronate sodium) injection instead of the currently approved 10-mg/mL injection. The injection is for intra-articular use in horses for treatment of joint dysfunction due to noninfectious synovitis associated with equine osteoarthritis. The drug is limited to use by or on the order of a licensed veterinarian. The supplemental NADA is approved as of September 30, 1998, and 21 CFR 522.1145 is amended in paragraph (a)(2) and by adding paragraph (f) to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

In addition, the sponsor has changed its name and address. The regulations are amended in 21 CFR 510.600(c) to