(**Note:** The text of Form 10–Q does not, and the amendments thereto will not appear in the Code of Federal Regulations.)

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10–Q

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PART II—OTHER INFORMATION

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Item 2. Changes in Securities and Use of Proceeds

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(d) If required pursuant to Rule 463 (17 CFR 230.463) of the Securities Act of 1933, furnish the information required by Item 701(f) of Regulation S–K (§ 229.701(f) of this chapter).

* * * * *

39. By amending Form 10–QSB (referenced in § 249.308b) by revising the caption to Item 2 of Part II, and by adding paragraph (d) to Item 2 of Part II preceding the Instruction to read as follows:

(**Note:** The text of Form 10–QSB does not, and the amendments thereto will not, appear in the Code of Federal Regulations.)

FORM 10–QSB

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PART II—OTHER INFORMATION

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Item 2. Changes in Securities and Use of Proceeds

* * * * *

(d) If required pursuant to Rule 463 (17 CFR 230.463) of the Securities Act of 1933, furnish the information required by Item 701(f) of Regulation S–B (§ 228.701(f) of this chapter).

* * * * *

40. By amending Form 10–K (referenced in § 249.310) by removing from General Instruction I.(c) the phrase ''General Instruction (J)(1)(a)'' and adding in its place ''General Instruction (I)(1)(a)'', by removing from the facing page the words ''(Fee Required)'' and ''(No Fee Required)'', and in Item 5 of Part II by designating the current text as paragraph (a) and by adding paragraph (b) to read as follows:

(**Note:** The text of Form 10–K does not, and the amendments thereto will not, appear in the Code of Federal Regulations.)

FORM 10–K

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PART II

Item 5. Market for Registrant's Common Equity and Related Stockholder Matters

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(b) If required pursuant to Rule 463 (17 CFR 230.463) of the Securities Act of 1933, furnish the information required by Item 701(f) of Regulation S–K (§ 229.701(f) of this chapter).

* * * * *

By amending Form 10–KSB (referenced in § 249.310b) by removing from the facing page the words ''(Fee Required)'' and ''(No Fee Required)'', and in Item 5 of Part II by designating the current text as paragraph (a) and by adding paragraph (b) to read as follows:

(**Note:** The text of Form 10–KSB does not, and the amendments thereto will not, appear in the Code of Federal Regulations.)

FORM 10–KSB

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PART II

Item 5. Market for Common Equity and Related Stockholder Matters

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(b) If required pursuant to Rule 463 (17 CFR 230.463) of the Securities Act of 1933, furnish the information required by Item 701(f) of Regulation S–B (§ 228.701(f) of this chapter).

* * * * *

By the Commission.

Dated: July 18, 1997.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 97–19444 Filed 7–23–97; 8:45 am]

BILLING CODE 8010–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 93F–0428]

Indirect Food Additives: Paper and Paperboard Components

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 α-(dinonylphenyl)-ω-hydroxy-poly(oxy-1,2-ethanediyl), containing 7 to 24 moles of ethylene oxide per mole of dinonylphenol, as a component of defoaming agents used in styrene-butadiene coatings for paper and paperboard intended to contact food. This action is in response to a food additive petition filed by PPG Industries, Inc.

DATES: Effective July 24, 1997; written objections and requests for a hearing by August 25, 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: Andrew J. Zajac, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3095.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the **Federal Register** of January 5, 1994 (59 FR 590), FDA announced that a food additive petition (FAP 3B4363) had been filed by PPG Industries, Inc., One PPG Pl., Pittsburgh, PA 15272 (formerly 440 College Park Dr., Monroeville, PA 15146). The petition proposed to amend the food additive regulations in § 176.200 *Defoaming agents used in coatings* (21 CFR 176.200) and § 176.210 *Defoaming agents used in the manufacture of paper and paperboard* (21 CFR 176.210) to provide for the use of α-(dinonylphenyl)-ω-hydroxy-poly(oxy-1,2-ethanediyl), containing 7 to 24 moles of ethylene oxide per mole of dinonylphenol, as a defoaming agent used in the production of paper and paperboard and coatings for paper and paperboard intended to contact food. The petitioner has subsequently withdrawn the request for approval of the use of the additive in the production of paper and paperboard and has requested that approval of the additive be limited to use in styrene-butadiene polymer coatings for paper and paperboard intended to contact 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 ethylene oxide and minute amounts of 1,4-dioxane as impurities resulting from its manufacture. These chemicals have been shown to cause cancer in test animals. Residual amounts of impurities are commonly found as constitutents of chemical products, including food additives.

II. 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 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 intended use of the additive, *Scott* v. *FDA*, 728 F.2d. 322 (6th Cir. 1984).

III. Safety of Petitioned Use of the Additive

FDA estimates that the petitioned use of the additive, α-(dinonylphenyl)-ω-hydroxy-poly(oxy-1,2-ethanediyl), containing 7 to 24 moles of ethylene oxide per mole of dinonylphenol, will result in exposure to no greater than 25 parts per billion (ppb) of the additive in the daily diet (3 kilogram (kg)) or an estimated daily intake (EDI) of 75 micrograms per person per day (μg/person/day) (Refs. 1 and 2).

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. 3), 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 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 ethylene oxide and 1,4-dioxane, the carcinogenic chemicals that may be present as impurities in the additive. The risk evaluation of ethylene oxide and 1,4-dioxane has two aspects: (1) Assessment of exposure to the impurities from the petitioned use of the additive; and (2) extrapolation of the risk observed in the animal bioassays to the conditions of exposure to humans.

A. Ethylene oxide

FDA has estimated the exposure to ethylene oxide from the petitioned use of the additive as a component of defoaming agents used in styrene-butadiene coatings for paper and paperboard to be no more than 0.25 part per trillion (pptr) in the daily diet (3 kg), or 0.75 nanogram (ng)/person/day (Refs. 1 and 2). The agency used data from a long-term rodent bioassay on ethylene oxide conducted for the Institute of Hygiene, University of Mainz, Germany (Ref. 4), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The author reported that the test material caused significantly increased incidence of squamous cell carcinomas in situ of the forestomach and carcinoma in situ of the glandular stomach in female rats.

Based on the agency's estimate that exposure to ethylene oxide will not exceed 0.75 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 1.5×10^{-9}, or 1.5 in a billion (Ref. 5). 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 petitioned use of the additive.

B. 1,4-Dioxane

FDA has estimated the exposure to 1,4-dioxane from the petitioned use of the additive as a component of defoaming agents used in styrene-butadiene coatings for paper and paperboard to be no more than 0.13 pptr of the daily diet (3 kg), or 0.39 ng/person/day (Refs. 1 and 2). The agency used data from a long-term rodent bioassay on 1,4-dioxane conducted by the National Cancer Institute (Ref. 6), to estimate the upper-bound limit of lifetime human risk from exposure to this chemical resulting from the petitioned use of the additive. The authors reported that the test material caused significantly increased incidence of squamous cell carcinomas in male and female rats and hepatocellular tumors in female rats and male and female mice.

Based on the agency's estimate that exposure to 1,4-dioxane will not exceed 0.39 ng/person/day, FDA estimates that the upper-bound limit of lifetime human risk from the petitioned use of the subject additive is 1.4×10^{-11}, or 14 in a trillion (Ref. 5). 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 petitioned use of the additive.

C. Need for Specifications

The agency has also considered whether specifications are necessary to control the amount of ethylene oxide and 1,4-dioxane 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 ethylene oxide and 1,4-dioxane may be expected to remain as impurities following production of the additive, the agency would not expect the impurities to become components of food at other than extremely low levels; and (2) the upper-bound limits of lifetime human risk from exposure to the impurities, even under worst-case assumptions, are very low (less than 1.5 in 1 billion).

IV. 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 component of defoaming agents used in styrene-butadiene coatings for paper and paperboard intended for contact with food is safe, and that the additive will achieve its intended technical effect. Therefore, the agency concludes that the regulations in § 176.200 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.

V. 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. No comments were received during the 30-day comment period specified in the filing notice for comments on the environmental assessment submitted with the petition.

VI. Objections

Any person who will be adversely affected by this regulation may at any time on or before August 25, 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.

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 June 19, 1995, from the Chemistry Review Branch (HFS–247), to the Indirect Additives Branch (HFS–216) entitled ''FAP 3B4363 (MATS No. 695; M 2.3 and M 2.4)-PPG Industries, Inc. Dinonylphenol-ethylene oxide adduct for use as a component of defoaming agents used in paper coatings and in the manufacture of paper and paperboard. Submissions dated 7–12–94, 10–4–94, and 11–1–94.''

2. Memorandum dated July 11, 1996, from the Chemistry Review Branch (HFS–247), to the Indirect Additives Branch (HFS–216) entitled ''FAP 3B4363 (MATS No. 695; M 2.4.1)-PPG Industries, Inc. Dinonylphenol-ethylene oxide adduct for use as a component of defoaming agents used in paper coatings. Telefax submissions dated 9–22–95 and 3–7–96.''

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

4. Dunkelberg, H., ''Carcinogenicity of Ethylene Oxide and 1,2-Propylene Oxide Upon Intragastric Administration to Rats,'' *British Journal of Cancer*, 46:924, 1982.

5. Memorandum dated July 24, 1996, from Indirect Additives Branch (HFS–216), to Sara H. Henry, Executive Secretary, Quantitative Risk Assessment Committee (HFS–308), entitled ''Estimation of the upper-bound lifetime risk from ethylene oxide and 1,4-dioxane - FAP 3B4363.''

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

List of Subjects in 21 CFR Part 176

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 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348, 379e).

2. Section 176.200 is amended in the table in paragraph (d)(3) by alphabetically adding a new entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 176.200 Defoaming agents used in coatings.

* * * * *

(d) * * *

(3) * * *

List of substances	Limitations
* * *	* * * *
α-(Dinonylphenyl)-ω-hydroxy-poly(oxy-1,2-ethanediyl), containing 7 to 24 moles of ethylene oxide per mole of dinonylphenol (CAS Reg. No. 9014–93–1).	For use only in defoaming agents for the production of styrene-butadiene coatings at a level not to exceed 0.05 percent by weight of the finished coating.
* * *	* * * *

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Dated: June 10, 1997.

William K.Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–19428 Filed 7–23–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 250 and 256

RIN 1010–AC04

Pipeline Right-of-Way Applications and Assignment Fees; Requirements for Filing of Lease Transfers

AGENCY: Minerals Management Service, Interior.

ACTION: Final rule.

SUMMARY: The Minerals Management Service (MMS) amends its regulations governing the filing fees charged for processing pipeline right-of-way applications and assignments, and applications for approval of instruments of transfer of a lease or interest. This amendment increases the filing fees for these documents, which will allow MMS to recover the full processing costs.

EFFECTIVE DATE: September 22, 1997.

FOR FURTHER INFORMATION CONTACT: John Mirabella, Engineering and Operations Division, at (703) 787–1607.

SUPPLEMENTARY INFORMATION: MMS last increased the filing fees for pipeline right-of-way applications and assignments on April 1, 1988. At that time, the fee for a pipeline right-of-way application was increased to $1,400, and the fee for a pipeline right-of-way assignment was increased to $50. MMS has not changed the $25 filing fee for instruments of transfer of a lease or interest since the administration of regulations concerning Outer Continental Shelf (OCS) minerals and rights-of-way was transferred to MMS from the Bureau of Land Management in 1982.

During the years since MMS last adjusted these filing fees, the costs to process these documents have increased. MMS conducted in-house cost analyses based on the costs of salaries and benefits, computer time, and overhead in each of the regional offices to determine the average processing cost for each of these documents. The results showed that MMS is undercharging for these services, and, therefore, MMS is increasing the fees.

This rule increases the filing fee for a pipeline right-of-way application from $1,400 to $2,350; the filing fee for a pipeline right-of-way assignment from $50 to $60; and the filing fee for instruments of transfer of a lease or an interest from $25 to $185.

MMS published a notice of proposed rulemaking (NPRM) on August 11, 1995 (60 FR 41034). We received eight comment letters responding to the proposed rule. The comments all opposed the increase in fees. The principal comments and MMS's responses are as follows:

Comment: Commenters opposed the large increase in the fee for transfer of leases. They pointed out that the MMS had proposed an increase of 640 percent. Comments suggested a lesser increase based on the increase in the Consumer Price Index (CPI) or the increase in the Council of Petroleum Accountants Society's (COPAS) Wage Index. Others suggested a specific amount.

Response: Under the Independent Offices Appropriation Act of 1952 (IOAA), 31 U.S.C. 9701, and Department of the Interior (DOI) implementing policy, MMS is required to charge the full cost for services which provide special benefits or privileges to an identifiable non-Federal recipient above and beyond those which accrue to the public at large. We do not have the option of choosing to charge less.

Comment: The bonus, royalty, and rental payments lessees make are more than sufficient to cover any fee increases that might be needed.

Response: Bonus, royalty, and rental payments are compensation for the right to explore for, develop, and produce oil and gas on the lease. Fees covering pipeline rights-of-way applications or transfers and fees covering transfers of leases provide additional benefits not covered by bonus, royalty, and rental payments.

Comment: MMS should improve its business practices and look to reduce costs internally before passing on costs to lessees.

Response: MMS is continuously looking for ways to improve efficiency and lower costs. This increase reflects both the effects of inflation and the effects of added complexity of reviewing lease transfers. These added complexities result from necessary bond reviews.

Comment: Establish a fee schedule for ''multiples'' of interests transferred when one lessee transfers a number of interests to another party (i.e., $X per 10 transfers). Also, establish a ceiling on the total cost for these types of ''bulk'' transfers.

Response: The new fees are based on the total cost of reviewing and approving many applications and requests for transfers. The fee charged for each transaction is an average. If MMS were to set up a system allowing a lesser fee for simple transfers or ''bulk'' transfers, then the fee for others would need to be higher. MMS chose to charge the same fee for all transactions rather than a higher fee for some transactions and a lower fee for others. A variable fee structure would be difficult to administer and would add unnecessary administrative costs.

Comment: MMS should not index the fees to the CPI. The commenter believed that with automatic increases in costs, MMS would not strive to control expenses or improve work efficiency, and lessees would be precluded from any future comment on fee increases. Others suggested the COPAS Wage Index as the appropriate choice of an index.

Response: We kept the proposed provision to allow future automatic adjustments in the amount of the fee based on the CPI ''U''. We believe that a broader inflation index such as the CPI ''U'' is a better indicator of changes in MMS costs than the suggested COPAS Wage Index which specifically reflects costs in the petroleum industry. (Note: the CPI ''U'' refers to the CPI for all urban consumers.)

However, in response to the comment, we revised the rule to allow MMS to increase the fee by a percentage equal to the percentage increase in MMS costs to process applications. MMS will attempt to minimize cost increases. The rule provides that if the percentage increase in MMS costs is greater than the percentage increase in the CPI ''U'', MMS will provide notice and opportunity for comment before changing the fee. Author: This document was prepared by John V. Mirabella, Engineering and Operations Division.

Executive Order (E.O.) 12866

This rule is a significant rule under E.O. 12866 and has been reviewed by the Office of Management and Budget (OMB). MMS estimates that the rule will cost industry approximately $670,000 per year. This is based on the average number of applications, assignments, and transfers handled by the Regions in the past.

E.O. 12988

DOI certified to OMB that this rule meets the applicable civil justice reform standards provided in sections 3(a) and 3(b)(2) of E.O. 12988.