85–02–05, Amendment 39–4984, and by adding a new AD to read as follows:

85-02-05 R1 The New Piper Aircraft, Inc.: Amendment 39–10189; Docket No. 84–CE–27–AD. Revises AD 85–02–05, Amendment 39–4984.

Applicability: The following model and serial number airplanes, certificated in any category:

Models	Serial numbers
PA-20, PA-20S, PA- 20-115, PA-20S- 115, PA-20-135, and PA-20S-135.	20–1 through 20– 1121.
PA-22, PA-22-108, PA-22-135, PA- 22S-135, PA-22- 150, PA-22S-150, PA-22-160, and PA-22S-160.	22–1 through 22– 9848.
PA-23 and PA-23- 160.	23–1 through 23– 2046.
PA-23-235, PA-23- 250, and PA-E23- 250.	27–1 through 27- 8154030.
PA-24, PA-24-250, and PA-24-260.	24-1 through 24- 5034.
PA-24-400 PA-25, PA-25-235, and PA-25-260.	26–1 through 26–148. 25–1 through 25- 8156024.
PA-30	30–1 through 30– 2000.
PA-31P	31P-1 through 31P-7730012.
PA-36-285, PA-36- 300, and PA-36- 375.	36–7360001 through 36–8302025.
PA-39 PA-44-180	39–1 through 39–162. 44–7995001 through 44–8195026.
PA-44-180T	44–8107001 through 44–8207020.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, repaired, or reconfigured in the area subject to the requirements of this AD. For airplanes that have been modified, altered, repaired, or reconfigured so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (d) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required within 100 hours time-in-service after March 1, 1985 (the effective date of AD 85–02–05, Amendment 39–4984) or prior to the next flight after the effective date of this AD, whichever occurs later, unless already accomplished.

To prevent airplane controllability problems while involved in ground operation because of improper brake operations, accomplish the following:

- (a) Install one of the following in a central location on the pilot's instrument panel in full view of the pilot.
- (1) A Piper part number 81090–02 placard; or
- (2) A Piper part number 683–107 placard.

Note 2: The above referenced placards both contain the following language:

"Warning No Braking Will Occur if Aircraft Brakes Are Applied While Parking Brake Handle is Pulled and Held"

- (b) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.
- (c) Installing the placard required by paragraph (a) of this AD may be performed by the owner/operator holding at least a private pilot certificate as authorized by section 43.7 of the Federal Aviation Regulations (14 CFR 43.7), and must be entered into the aircraft records showing compliance with this AD in accordance with section 43.9 of the Federal Aviation Regulations (14 CFR 43.9).
- (d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Atlanta Aircraft Certification Office (ACO), One Crown Center, 1895 Phoenix Boulevard, suite 450, Atlanta, Georgia 30349.
- (1) The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Atlanta ACO.
- (2) Alternative methods of compliance approved in accordance with AD 85–02–05 (revised by this action) are considered approved as alternative methods of compliance with this AD.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Atlanta ACO.

- (e) All persons affected by this directive may examine information pertaining to this document at the FAA, Central Region, Office of the Regional Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.
- (f) This amendment (39–10189) becomes effective on November 21, 1997.

Issued in Kansas City, Missouri, on October 27, 1997.

Mary Ellen A. Schutt,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service. [FR Doc. 97–28983 Filed 10–31–97; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 93F-0461]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Milk-Clotting Enzymes

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 aspartic proteinase enzyme preparation produced by pure culture fermentation of *Aspergillus oryzae* modified by recombinant deoxyribonucleic (DNA) techniques to contain the gene for aspartic proteinase enzyme from *Rhizomucor miehei* for use as a milk-clotting enzyme in the production of cheese.

DATES: The regulation is effective November 3, 1997; written objections and requests for a hearing by December 3, 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: Wendy J. Dixon, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3090.

SUPPLEMENTARY INFORMATION:

In a notice published in the Federal Register of January 21, 1994 (59 FR 3365), FDA announced that a food additive petition (FAP 4A4406) had been filed by Novo Nordisk Bioindustrials, Inc., proposing that the food additive regulations be amended to provide for the safe use of aspartic proteinase enzyme preparation produced by pure culture fermentation of A. oryzae modified by recombinant DNA techniques to contain the gene for aspartic proteinase enzyme from R. *miehei* for use in the production of cheese. Although Novo Nordisk Bioindustrials, Inc., submitted FAP 4A4406, while the petition was under review, Gist-Brocades International B. V. purchased the dairy enzyme business from Novo Nordisk, at which time, the responsibility for the petition transferred to Gist-Brocades International B. V.

I. Evaluation of Safety of the Petitioned Use of the Additive

A. Aspergillus Oryzae

The host organism for production of aspartic proteinase is the fungus A. oryzae. A. oryzae has had a long history of use, greater than 2,000 years, in the production of enzymes, e.g., koji and αamylase, used in the fermentation and processing of food products, such as soy-sauce, miso, sake, baked goods, and brewery products (Refs. 1 and 2). The nonpathogenicity and nontoxigenicity of this microbe to humans and its inability to produce antibiotics is welldocumented in the literature (Refs. 1, 3, and 4). This conclusion regarding the nonpathogenicity and nontoxigenicity of this microbe is consistent with a recent evaluation of the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) (Ref. 5). JECFA evaluated the current uses of A. oryzae and enzyme preparations therefrom and concluded that the amylases and proteases from A. oryzae that were included in JECFA's review should be regarded as foods and thus, are safe for use in food processing.

The petitioner submitted a study to investigate the pathogenic potential of five strains of *A. oryzae*, including the parental strain and four recombinant strains; one of the strains tested is the subject of this petition. FDA evaluated this study and concluded that the recombinant strains of A. oryzae, as well as the unmodified parental strain, demonstrated no pathogenicity for mice when spores were inoculated in large numbers. Previously, A. oryzae has been the subject of evaluations performed by FDA, and based on those evaluations FDA concluded that the spores of two strains of A. oryzae are nonpathogenic to mice (Ref. 6). Therefore, FDA concludes that the recombinant strain of A. oryzae that is the subject of this petition is nonpathogenic and nontoxigenic (Ref. 3).

B. Rhizomucor Miehei

R. miehei, originally named Mucor miehei (Ref. 7), is the microorganism used as the source of the genetic material for the aspartic proteinase enzyme that is the subject of FAP 4A4406. Enzyme preparations derived from R. miehei (aspartic proteinase, or esterase-lipase activity produced by pure culture fermentation of R. miehei (as M. miehei)) are food additives that are approved for use in cheese production under §§ 173.150(a)(4) and 173.140 (21 CFR 173.150(a)(4) and 173.140), respectively.

C. Aspartic Proteinase Preparation

As discussed above, aspartic proteinase preparation produced by pure culture fermentation of R. miehei for use as a milk-clotting agent in the production of cheese is an approved food additive under § 173.150(a)(4). The petitioner has submitted the following evidence to demonstrate that it has cloned full length copies of the aspartic proteinase gene from R. miehei into A. oryzae: (1) DNA sequencing information, whereby the cloned putative aspartic proteinase gene was shown to have the same nucleotide sequence that encodes the amino acid sequence of the *R. miehei* aspartic proteinase; and (2) nucleic acid hybridization studies whereby the cloned DNA fragments were shown to hybridize (i.e., specifically bind) with complementary DNA from the aspartic

proteinase gene.

To further confirm the identity of the aspartic proteinase cloned into A. oryzae, the petitioner provided information on the sodium dodecyl polyacrylamide gel electrophoresis (SDS-PAGE)1 relative mobility of recombinant aspartic proteinase and aspartic proteinase from R. miehei, with and without treatment by endoglucosidase H (an enzyme that removes most glycosyl moieties from proteins). The results from this study establish that untreated aspartic proteinase from recombinant A. orvzae has a lower relative mobility than untreated aspartic proteinase from *R. miehei*. However, after pretreatment with endoglucosidase H, the aspartic proteinase preparations from both recombinant A. oryzae and R. miehei have an identical SDS-PAGE relative mobility. This is higher than the mobilities of either of the untreated forms of aspartic proteinase. These results show that aspartic proteinase from A. oryzae or R. *miehei* is glycosylated but when the *R*. miehei gene for aspartic proteinase is expressed in A. oryzae, the aspartic proteinase enzyme is more extensively glycosylated (Ref. 8).

FDA finds that glycosylation of the aspartic proteinase enzyme does not raise any safety concerns. Glycosylation is characteristic of many proteins produced in the cells of eukaryotic organisms, which include higher plants and animals, and fungi, such as A. oryzae and R. miehei (Ref. 9). However, the type and amount of glycosyl moieties attached to glycoproteins

varies, even among closely related organisms (Ref. 10). Therefore, proteins with identical amino acid sequences may have different amounts and types of glycosylation when produced in different eukaryotic organisms, such as A. oryzae and R. miehei. Because A. oryzae is a common, nonpathogenic, nontoxigenic organism that has a safe history of use in the production of food processing enzymes (Refs. 1 and 3), the agency finds that the more extensively glycosylated aspartic proteinase enzyme from recombinant A. oryzae is as safe as the less extensively glycosylated aspartic proteinase enzyme from R. miehei.

The petitioner submitted several toxicological studies that address the safety of the petitioned aspartic proteinase preparation. These include: (1) Short term and subchronic toxicity studies in both rats and dogs; (2) a teratogenicity study in rats; and (3) genotoxicity studies, including tests for mutagenic activity in Salmonella typhimurium and mammalian cells, as well as tests for chromosome-damaging activity in human lymphocytes. FDA has reviewed these studies and concludes that the petitioned aspartic proteinase preparation does not raise any toxicity concerns at the expected level of consumption nor does it have any mutagenic potential (Refs. 6, 11, and 12).

D. Source of Impurities

Enzyme preparations used in food are usually not chemically pure, but contain cellular and processing material. The nature and amounts of these impurities in the finished enzyme preparation depend on the organism from which the enzyme preparation is produced (the production organism), the fermentation materials and methods used to grow the production organism, and the materials and methods used to generate the finished enzyme preparation. Thus, the question is whether the production organism or the manufacturing methods used to grow the production organism or to generate the finished enzyme preparation from recombinant A. oryzae, will introduce impurities that raise concerns about the safety of the enzyme preparation. In addition, § 173.150(c) states that the milk-clotting enzyme preparation shall be produced by a process that completely removes the generating organism from the milkclotting enzyme product. The agency concludes that the petition contains information demonstrating that the manufacturing process includes procedures to ensure that the production organism is completely removed from the enzyme preparation

¹ SDS-PAGE is a technique that enables one to compare the relative molecular weight of proteins based on their rate of migration through the gel. The SDS-PAGE relative mobility of a protein is directly related to its molecular weight.

during the manufacturing (Refs. 3 and 13).

One issue raised by the use of recombinant DNA techniques is the potential transfer of DNA encoding for extraneous proteins along with the gene of interest (i.e., aspartic proteinase), thereby contaminating the enzyme preparation. As a matter of current good manufacturing practice, manufacturers using recombinant DNA technology should ensure that they have not inadvertently cloned extraneous protein-encoding DNA along with the aspartic proteinase gene that may lead to contamination of the aspartic proteinase enzyme preparation. Such assurance can come from reviewing the details of the cloning steps, which include the origin and sequence of the DNA fragments used in the cloning, and full characterization of the final genetic constructs via techniques such as DNA sequencing.

The petition contains information demonstrating that the petitioner evaluated the cloning process to ensure that the final cloning product, i. e., the DNA with the aspartic proteinase gene and other components to ensure accurate expression of the gene, used in the development of the recombinant A. oryzae was accurately constructed. As mentioned above, the petitioner submitted evidence to demonstrate that it cloned full length copies of the aspartic proteinase gene from R. miehei into A. oryzae. In addition to the aspartic proteinase gene, the recombinant A. oryzae strain contains a marker gene conferring resistance to ampicillin (amp^r), a clinically useful antibiotic, as well as a marker gene encoding the enzyme acetamidase (amdS), which permits the transformed strain to utilize acetamide as a nitrogen or carbon source. The petitioner states that the only transgenes expressed in the production organism, A. oryzae, are the aspartic proteinase transgene and the amdS transgene. Aspartic proteinase is secreted into the culture medium from which the enzyme preparation is produced while the enzyme acetamidase is not. Therefore, the agency concludes that the acetamidase is effectively removed when the production cells are discarded during processing (Ref. 13).

The expression of the *amp*^r gene is controlled by a promoter, a region of DNA that is a major component in the regulation of a gene. In general, bacterial promoters do not function in higher organisms, including the fungus *A. oryzae*. Because expression of the *amp*^r gene is controlled by a bacterial promoter, this gene is not expected to be expressed in the production organism,

A. oryzae. The agency has considered the potential consequences if expression of the amp^r transgene were to occur in the production organism. The petitioner noted that the enzyme preparation is produced from the fermentation supernatant and that in the process, intact cells are removed. Therefore, even if expression of the amp^r gene takes place, the gene product would be sequestered within the intact cells and therefore, would not be present in the fermentation supernatant, which is the source of the aspartic proteinase enzyme preparation. Accordingly, the agency concludes that any amp^r gene product would effectively be removed from the enzyme preparation (Ref. 13)

Finally, FDA notes that § 173.150(b) stipulates that the microbial milkclotting enzyme listed in the food additive regulations should be produced using a production strain that is nonpathogenic and nontoxic in man or other animals. For example, if the DNA inserted by recombinant methodology were to encode a toxic substance that would render the enzyme preparation unsafe, the resulting aspartic proteinase preparation would not conform with the prescribed conditions under § 173.150, and therefore, food processed with the improperly manufactured enzyme preparation would be deemed adulterated.

FDA concludes that, when the aspartic proteinase preparation is manufactured in conformity with § 173.150, there is no basis for concern regarding the possibility that the aspartic proteinase preparation will be contaminated by the products of extraneous protein-encoding DNA (e.g., products of *amdS* and *amp^r* genes) inserted along with the aspartic proteinase gene in *A. oryzae* (Ref. 13).

Furthermore, FDA concludes, having considered the evidence concerning the production organism and the processing steps to derive the aspartic proteinase preparation, that *A. oryzae* containing aspartic proteinase gene from *R. miehei* is safe for use as a source of food-grade aspartic proteinase preparations, and that impurities resulting from the use of *A. oryzae* containing aspartic proteinase gene from *R. miehei* in the production of aspartic proteinase preparation will not affect the safety of the aspartic proteinase preparation.

II. Conclusion

The agency finds that the principal active ingredient, i.e., aspartic proteinase, in the aspartic proteinase enzyme preparation, is the same as that in the milk-clotting enzyme preparation from *R. miehei*, and that when the preparation is manufactured in

accordance with the conditions of use listed in § 173.150, the source organism and manufacturing process will not introduce impurities that may render the use of the enzyme preparation unsafe.

The agency has evaluated the data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of aspartic proteinase enzyme preparation from *A. oryzae* containing the aspartic proteinase gene from *R. miehei* is safe and that the additive will achieve its intended technical effect. Therefore, the regulation in § 173.150 should be amended.

III. Inspection of Documents

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 December 3, 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. Barbesgaard, P., H. P. Heldt-Hansen, and B. Diderichsen, "On the Safety of Aspergillus oryzae: A Review," Applied Microbiology and Biotechnology, 36:569–572, 1992.
- 2. "Biotechnologies and Food: Assuring the Safety of Foods Produced by Genetic Modification," *Regulatory Toxicology and Pharmacology*, 12 (3):S114–S128, 1990.

3. Memorandum from J. Madden, FDA, to D. Keefe, FDA, April 11, 1994.

- 4. Gray, W. D., *The Use of Fungi as Food and in Food Processing*, pp. 42–100, CRC Press, Cleveland, OH, 1970.
- 5. Joint FAO/WHO Expert Committee on Food Additives. "Toxicological Evaluation of Certain Food Additives," 31st Meeting, Geneva, February 16–25, 1987.
- 6. Memorandum from H. C. A. Chang, FDA, to D. Keefe, FDA, March 14, 1994.
- 7. Shipper, M. A. A., "On the Genera *Rhizomucor* and *Parasitella*," *Studies in Mycology*, 17:53–65, 1978.
- 8. Cristensen, T. et al., "High Level Expression of Recombinant Genes in Aspergillus oryzae," Bio/Technology, 6:1419–1422, 1988.
- 9. Herrman, J. L. et al., "Bacterial Glycoproteins: A Link Between Glycosylation and Proteolytic Cleavage of a 19 kDa Antigen from *Mycobacterium tuberculosis*," *EMBO Journal*, 15:3547–3554, 1996.
- 10. Grinna, L. S., and J. F. Tschopp, "Size Distribution and General Structural Features of N-linked Oligosaccharides from the Methylotrophic Yeast, *Pichia pastoris*," *Yeast*, 5 (2):107–115, 1989.
- 11. Memorandum from S. E. Carberry, FDA, to D. Keefe, FDA, January 5, 1995.
- 12. Memorandum from H. C. A. Chang, FDA, to D. Keefe, FDA, February 6, 1995.
- 13. Memorandum from T. A. Cebula, FDA, to D. Keefe, FDA, April 4, 1995.

List of Subjects in 21 CFR Part 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.150 is amended by adding paragraph (a)(5) to read as follows:

§ 173.150 Milk-clotting enzymes, microbial.

(a) * * *

(5) Aspergillus oryzae modified by recombinant deoxyribonucleic (DNA) techniques to contain the gene coding for aspartic proteinase from Rhizomucor miehei var. Cooney et Emerson as defined in paragraph (a)(4) of this section, and classified as follows: Class, Blastodeuteromycetes (Hyphomycetes); order, Phialidales (Moniliales); genus, Aspergillus; species oryzae.

Dated: October 20, 1997.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 97-29048 Filed 10-31-97; 8:45 am] BILLING CODE 4160-01-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[CA 083-0053a; FRL-5911-4]

Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Diego County Air Pollution Control District, Ventura County Air Pollution Control District

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action on revisions to the California State Implementation Plan (SIP). These revisions concern rules from the San Diego County Air Pollution Control District (SDCAPCD) and the Ventura County Air Pollution Control District (VCAPCD). This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of volatile organic compounds (VOCs) in accordance with the requirements of the Clean Air Act,

as amended in 1990 (CAA or the Act). The revised rules control VOC emissions from metal container, metal closure, and metal coil coating operations and marine vessel coating operations. Thus, EPA is finalizing the approval of these revisions into the California SIP under provisions of the CAA regarding EPA action on SIP submittals, SIPs for national primary and secondary ambient air quality standards and plan requirements for nonattainment areas.

DATES: This action is effective on January 2, 1998 unless adverse or critical comments are received by December 3, 1997. If the effective date is delayed, timely notice will be published in the **Federal Register**.

ADDRESSES: Comments must be submitted to Andrew Steckel at the Region IX office listed below. Copies of the rule revisions and EPA's evaluation report for each rule are available for public inspection at EPA's Region IX office during normal business hours. Copies of the submitted rule revisions are available for inspection at the following locations:

Rulemaking Office (AIR-4), Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105

Environmental Protection Agency, Air Docket (6102), 401 "M" Street, S.W., Washington, D.C. 20460

California Air Resources Board, Stationary Source Division, Rule Evaluation Section, 2020 "L" Street, Sacramento, CA 92123–1095

San Diego County Air Pollution Control District, 9150 Chesapeake Drive, San Diego, CA 92123–1096

Ventura County Air Pollution Control District, 702 County Square Drive, Ventura, California 93003.

FOR FURTHER INFORMATION CONTACT: Jerald S. Wamsley, Rulemaking Office, AIR-4, Air Division, U.S. Environmental Protection Agency, Region IX, 75 Hawthorne Street, San Francisco, CA 94105, Telephone: (415) 744-1226

SUPPLEMENTARY INFORMATION:

I. Applicability

The rules being approved into the California SIP include SDCAPCD's Rule 67.4, Metal Container, Metal Closure, and Metal Coil Coating Operations, and VCAPCD's Rule 74.24, Marine Vessel Coating Operations. These rules were submitted by the California Air Resources Board (CARB) to EPA on October 18, 1996 and May 24, 1994, respectively.