(iii) The basis upon which the loss resulted from a qualified agricultural loan.

(7) A certification by the bank's chief executive officer that there is no evidence that the losses resulted from fraud or criminal abuse by the bank, its officers, directors, or principal shareholders;

(8) A copy of a resolution by the bank's Board of Directors authorizing submission of the proposal; and

(9) Such other information as the Accepting Official may require.

§ 35.8 Revocation of eligibility.

The failure to comply with any condition in an acceptance or the capital restoration plan is grounds for revocation of acceptance for loss amortization and for an administrative action against the bank under 12 U.S.C. 1818(b). Additionally, acceptance of a bank for loss amortization will not foreclose any administrative action against the bank that the OCC may deem appropriate.

Date: July 19, 1988.

Robert L. Clarke,

Comptroller of the Currency.

[FR Doc. 88-16684 Filed 7-27-88; 8:45 pm]

BILLING CODE 4810-33-M

Customs Service

19 CFR Part 10

[T.D. 88-45]

Customs Regulations Amendment Concerning Reciprocal Privileges Extended To Aircraft of Japan

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations by changing the list of countries whose aircraft are exempt from the payment of Customs duties and internal revenue taxes on supplies and equipment withdrawn from Customs or internal revenue custody for use by aircraft. The amendment indicates that aircraft of Japanese registry are no longer entitled to free withdrawal of ground support equipment.

Prior to 1986, Japan had been extending aircraft of U.S. registry exemption privileges in connection with international commercial operations which were substantially reciprocal to those exemption privileges the U.S. provided to aircraft of foreign registry by sections 309 and 317 of the Tariff Act of 1930, as amended. Accordingly, the Customs Regulations provided that aircraft of Japanese registry were entitled to free withdrawal privileges. However, the Department of Commerce has informed Customs that Japan is no longer extending the exemption privileges to ground support equipment of U.S. aircraft. Accordingly, the U.S. will no longer exempt aircraft of Japanese registry from the payment of duties and taxes when their ground support equipment is withdrawn from Customs or internal revenue custody.

EFFECTIVE DATE: July 28, 1988.

FOR FURTHER INFORMATION CONTACT: William G. Rosoff, Entry Rulings Branch, (202) 566-6040.

SUPPLEMENTARY INFORMATION:

Background

Sections 309 and 317, Tariff Act of 1930, as amended (19 U.S.C. 1309 and 1317), provide that foreign-registered aircraft engaged in foreign trade may withdraw articles of foreign or domestic origin for use as supplies (including equipment), ground equipment, maintenance or repair of the aircraft from Customs or internal revenue custody without the payment of Customs duties and/or internal revenue taxes. This privilege is granted if the Secretary of Commerce finds and advises the Secretary of the Treasury, that the country in which the foreign aircraft is registered allows substantially reciprocal privileges to U.S. registered aircraft. Section 10.59(f), Customs Regulations (19 CFR 10.59(f)), lists those countries whose aircraft have been found to be entitled to these privileges.

By virtue of the authority vested in the President by section 5 of the Act of May 28, 1908, 35 Stat. 425, as amended (46 U.S.C. 104), the President has delegated the authority to issue this list of nations to the Secretary of the Treasury by E.O. 10289, September 17, 1951. By Treasury Department Order 165-25, the Secretary of the Treasury delegated authority to the Commissioner of Customs to prescribed regulations relating to § 10.59(f) and other sections of the Customs Regulations relating to lists of countries entitled to preferential treatment in Customs matters because of reciprocal privileges accorded to vessels and aircraft of the U.S. Subsequently, by Customs Delegation Order No. 66 (T.D. 82-201), dated October 13, 1982, the Commissioner delegated authority to amend these sections to the Assistant Commissioner (Commercial Operations), who redelegated this authority to the Director, Office of Regulations and Rulings, who then redelegated it to the Chief, Regulations and Disclosure Law Branch.

In accordance with 19 U.S.C. 1309(d), the Secretary of Commerce previously found, and advised the Secretary of the Treasury that Japan allowed privileges substantially reciprocal to those provided for in 19 U.S.C. 1309 and 1317 to aircraft registered in the U.S. and engaged in foreign trade. Therefore, by T.D. 53550, Japan was listed in § 10.59(f), Customs Regulations and corresponding privileges were extended to aircraft registered in Japan engaged in foreign trade.

The Commerce Department has not determined, and conveyed to the Customs Service, that Japan no longer exempts ground support equipment of aircraft of U.S. registry from taxes and duties. The finding became effective on August 1, 1986. This document amends § 10.59(f), Customs Regulations (19 CFR 10.59(f)), by changing the list of countries whose aircraft are exempt from the payment of Customs duties and internal revenue taxes on suppliers and equipment withdrawn from Customs or internal revenue custody for use by aircraft to indicate that Japan has discontinued its exemption regarding ground support equipment.

Executive Order 12291

This document does not meet the criteria for a "major rule" as defined in section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Regulatory Flexibility Act

Pursuant to the provisions of section 605(b) of the Regulation Flexibility Act (Pub. L. 96-354, 5 U.S.C. 601, *et seq.*), it is certified that the change set forth in this document will not have a significant economic impact on any substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Inapplicability of Public Notice and Delayed Effective Date Requirements

Because the subject matter of this document does not constitute a departure from established policy or procedures but merely announces the recision of a previously granted exemption for which there is a statutory basis, it has been determined, pursuant to 5 U.S.C. 553(b)(B), that notice and public procedure thereon are unnecessary. As Japan has been found by the Department of Commerce to have discontinued its exemption privileges reagarding ground support equipment in 1986, a delayed effective date is not appropriate.

Drafting Information

The principal author of this document was Lee H. Kramer, Regulations and Disclosure Law Branch, Office of Regulations and Rulings, Customs Headquarters. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 10

Customs duties and inspection, Imports, Exports, Oil imports, Petroleum.

Amendment To The Regulations

Part 10, Customs Regulations (19 CFR Part 10), is amended as set forth below:

PART 10—ARTICLES CONDITIONALLY FREE, SUBJECT TO A REDUCED RATE, ETC.

1. The general authority citation for Part 10 and specific relevant authority continues to read as follows:

Authority: 19 U.S.C. 66, 1202, 1481, 1484, 1498, 1623, 1624.

* * * * *

2. Section 10.59 also issued under 19 U.S.C. 1309, 1317.

* * * * *

§ 10.59 [Amended]

2. In the list of countries in § 10.59(f), the listing for Japan is amended by adding ", 88–45" under the column marked "Treasury Decision(s)" and by adding "not applicable to ground support equipment as of August 1, 1986" in the column marked "Exceptions if any, as noted—".

Dated: July 22, 1988.

Kathryn C. Peterson,

Chief, Regulations and Disclosure Law Branch.

[FR Doc. 88–17000 Filed 7–27–88; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 82F–0295]

Food Additives Permitted For Direct Addition To Food For Human Consumption; Acesulfame Potassium

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of acesulfame potassium as a nonnutritive sweetener. This action responds to a petition filed by American Hoechst Corp.

DATES: Effective July 28, 1988; objections and requests for hearing by August 29, 1988. The Director of the Office of the Federal Register approves the incorporation by reference of certain publications at 21 CFR 172.800(b) effective July 28, 1988.

ADDRESS: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia J. McLaughlin, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION:

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I. Summary of the Petition

In a notice published in the **Federal Register** of October 15, 1982 (47 FR 46139), FDA announced that a peitition (FAP 2A3659) has been filed by American Hoechst Corp. (now Hoechst Celanese Corp.), Route 202–206 North, Somerville, NJ 08876, proposing that the food additive regulations be amended to provide for the safe use of acesulfame potassium (potassium salt of 6-methyl–1,2,3–oxathiazine-4(3*H*)-one-2,2-dioxide) as a nonnutritive sweetener.

Acesulfame potassium has also been called "acesulfame K" or "acetosulfam," and is a derivative of acetoacetic acid. It can be manufactured by reacting *tert*-butyl acetoacetate with fluorosulfonyl isocyanate. The reaction product is converted to an amide which is then cyclized with concomitant removal of fluoride and formation of the potassium salt. The sweetener is water soluble and is stable at normal temperatures and moderate pH. It is approximately 200 times sweeter than sucrose based on comparison to a 3 percent aqueous solution of sucrose.

This petition has requested the use of acesulfame potassium as a table-top sweetener and as an ingredient in chewing gum, confections, hard candy, soft candy, and dry bases for beverages, instant coffee and tea, gelatins, puddings, pudding desserts, and dairy product analogs. In this final rule, the agency is listing all of the requested uses except confections, hard candy, and soft candy. Before acting on these uses, FDA must first consider further whether acesulfame potassium or other nonnutritive sweeteners can be listed for use in confectionary under section 402(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(d)(3)). Section 402(d)(3) bars the use of any nonnutritive substance in confectionary, unless the subtance is used for some practical functional purpose and does not promote deception of the consumer. In interpreting section 402(d)(3), the agency's position has been that the use of nonnutritive artificial sweeteners in confectionary for the purpose of caloric reduction is not a practical functional purpose. The agency is reexamining this interpretation.

The petitioner submitted a series of toxicity studies concerned with the safety of acesulfame potassium. These include studies on reproduction in rats and rabbits, teratology in rats, and mutagenicity. There are reports on metabolism, kinetics, distribution, and elimination studies using rats, pregnant rats, dogs, pigs, and humans. There are also various pharmacological investigations and a study in rats with artificially induced diabetes. There are reports from studies done concerning acute toxicity, subchronic toxicity, chronic toxicity, and potential carcinogenicity.

Data from four long-term studies were submitted. One is a 2-year toxicity study in beagle dogs in which groups of four male and four female dogs were fed 0, 90, 300, or 900 milligrams per kilogram of acesulfame potassium in their diet. Another is a carcinogenicity study in Swiss mice. Diets containing 0, 0.3, 1.0, or 3.0 percent of the test compound were fed to groups containing 100 male and 100 female mice. There are two long-term studies in rats; both are chronic toxicity and carcinogenicity studies with in utero exposure. In each case, 0, 0.3, 1.0, or 3.0 percent acesulfame potassium in the diet was fed to groups containing 60 females and 60 males. The first rat study was conducted with the CIVO-bred Wistar strain. The second rat study used CPB-WU Wistar rats. The agency discusses its evaluation of these studies below.

II. Evaluation Of The Petition

A. Estimated Daily Intake

In determining whether the proposed use of an additive is safe, FDA considers whether an individual's estimated daily intake of the additive will be less than the acceptable daily intake established from safety data. The

agency determines the estimated daily intake for various age groups by making projections based on the amount of additive proposed for use in particular foods and on data about the consumption levels of each particular food. The use levels of acesulfame potassium considered by the agency to estimate consumer exposure are supported by analytical data and taste panel testing reported in the petition. The petitioner also submitted survey information on the consumption of the food types for which use of acesulfame potassium was requested (Ref. 1).

The agency commonly uses the estimated daily intake for the 90th percentile consumer of a food additive as a measure of high chronic exposure because that level of consumption is significantly above the intake of the average consumer, thus providing an added margin of safety with respect to the acceptable daily intake for those individuals who regularly consume food containing the additive. For the requested food uses of acesulfame potassium, the agency has determined the 90th percentile estimated daily intake to be 1.6 milligrams per kilogram of body weight (for further details on this estmate see Ref. 1).

B. Safety Studies

The metabolism studies of acesulfame potassium revealed no evidence that this substance is metabolized. The reproduction and teratology studies produced no evidence of compound-related teratogenic or adverse reproductive effects. The mutagenicity studies did not indicate any genotoxic effects from acesulfame potassium. None of the various short-term studies showed any untoward adverse effects from acesulfame potassium. The 2-year toxicity study in beagle dogs did not show any toxic effects associated with the consumption of acesulfame potassium.

For the carcinogenicity study in mice, the petitioner had a consulting pathologist, as well as the testing laboratory, review the data and microslides. The testing laboratory, the consulting pathologist, and the agency all concluded that the data did not reveal any association between neoplasms and use of the substance, or between any other adverse effects and use of the substance (Ref. 2). Lymphocytic leukemia was reported as increased in the high-dose female mice, but the incidences were within the range of spontaneous incidences with this strain in the laboratory. The control, low-, and mid-dose groups had incidences of 1 percent and the high-dose group had 4 percent incidence. The historical control groups from eight other studies at this testing laboratory had an overall incidence of 5.2 percent. In rodent studies, lymphocytic leukemia should more properly be considered within the context of the other lymphoreticular neoplasms such as lymphosarcoma and reticulum cell sarcoma (Ref. 3) instead of separately as was done here. The agency concludes that there was no increase in neoplastic disease of the lymphoreticular system in mice due to treatment with acesulfame potassium. FDA also finds that this study met the minimum standards of testing for length of treatment and degree of survival.

For the first of the two long-term rat studies submitted, the testing laboratory stated that the results showed a slightly higher incidence, and a somewhat earlier appearance, of lymphoreticular pulmonary neoplasms (reticulm cell sarcomas) in the mid- and high-dose groups of both male and female rats than in the concurrent control group. The laboratory discussed several reasons to support its conclusion that these effects were not caused by treatment.

The agency concludes that this study, is inadequate to demonstrate safety and does not establish a carcinogenic effect of acesulfame potassium (Refs. 2 and 4). A major deficiency in the study is the fact that only 20 of the 60 rats in the control and high dose groups were subject to a complete histopathological examination, thereby limiting the proper interpretation of the results of the study. Moreover, the presence of extensive, severe chronic respiratory disease in the lungs of rats of all groups confounded diagnosis and interpretation of lung lesions in these animals. Generally, reticulum cell sarcomas in most strains of rats arise from lymph nodes and disseminated to many organs (Ref. 5). However, in the CIVO-bred Wistar rats, the occurrence of reticulum cell sarcomas in the lung seems to be linked with the presence of chronic respiratory disease (Ref. 5). These neoplasms in the CIVO strain are generally localized in the lungs and do not disseminate to other organs or tissues. Reticulum cell sarcomas are known to occur spontaneously in this strain of rat; incidences as high as 32 percent had been reported in untreated CIVO-bred Wistar rats (Ref. 2). These findings on the lymphoreticular neoplasms observed in treated and control rats from this study reinforce the agency's judgment that these neoplasms were not caused by acesulfame potassium treatment and that, therefore, the study is inadequate and does not provide a basis for assessing the carcinogenicity of the compound.

Because the first study was not adequate for the safety evaluation of a prospective food additive, a second long-term rat study was conducted. In the original report by the testing laboratory on this study, submitted with the initial petition, tissues from some of the animals were reviewed by the study pathologist of the performing laboratory and the remainder were reviewed by a consulting pathologist. This division of labor resulted in inconsistencies in the diagnostic criteria applied to the observations reported in the study. Although the data appeared to show treatment-related differences in a few of the observations, these were subsequently found to be due to the different way categories of lesions were summarized. This was shown when the petitioner, in response to the agency's request for more detailed and explicit listings of the results of the study, had all the data and microscopic slides reviewed by a consulting pathologist, who prepared a new report.

After a comprehensive review of the data from this second study, the agency has concluded that it is adequate for the safety evaluation of a food additive and that there is no association between the occurrence of neoplasms and treatment with acesulfame potassium (Ref. 2). Moreover, these rats did not show lymphoreticular neoplasms in the lungs or lymphoreticular disease in any other organs that could be ascribed to treatment. The highest level fed, 3 percent of the diet, produced no adverse toxic effects.

Among the issues in the initial review that received attention were differences in incidence of mammary gland neoplasms in the female rats. Most of the mammary tumors were fibroadenomas; there incidences in the female rats were: Control group—17 of 56 rats examined (30.4 percent); 0.3 percent test compound—26 of 60 (43.3 percent); 1.0 percent test compound—28 of 59 (47.5 percent); 3.0 percent test compound—28 of 59 (47.5 percent) (Ref. 6). The mammary gland neoplasms other than fibroadenomas were few in number and were distributed randomly among the different groups. The incidences of mammary gland hyperplasia were similar and uniformly high in all groups of treated famales and in the control females. Thus, the occurrence of mammary gland hyperplasia was unrelated to treatment with acesulfame potassium.

The agency concludes that there was no association between the occurrence of mammary gland neoplasms and

treatment with acesulfame potassium. This conclusion is based on the following:

(1) Fibroadenomas are a common old age tumor in this strain of rats and their incidence is variable.

(2) The incidence of mammary fibroadenomas in female control rats from seven comparable studies, performed at this testing laboratory around the same time period as the acesulfame potassium study, is 250 of 452 or 55.3 percent (Ref. 6). This incidence is higher than the incidences for any of the treated groups in the acesulfame potassium study and is much higher than that for the concurrent control group. The concurrent control group had an unusually low incidence of these tumors.

(3) In the treated groups, the lack of a dose response in incidences of fibroadenomas, as well as of all mammary tumors and of hyperlasia, is evidence that there is not a treatment-related effect of the sweetener on the incidence of fibroadenomas.

(4) There was no evidence of progressive stages of mammary gland neoplasms (hyperplasia to malignant neoplasms) that would indicate a treatment-related induction of tumors.

The reproduction and teratology studies, and the long-term safety studies did not show any toxic effects due to treatment with acesulfame potassium. From the highest feeding level in the long-term rat study, 3 percent acesulfame potassium, the agency, using a 100-fold safety factor, finds that the acceptable daily intake in 15 milligrams per kilogram body weight. This acceptable daily intake level is well above the expected intake for the food uses requested.

III. Comments

The Center for Science in the Public Interest (CSPI), a consumer advocacy group, wrote to the agency to express its concerns about the testing and safety of this sweetener, and included a copy of a newsletter article it had published on this subject. Several individuals also wrote to the agency echoing the concerns in the newsletter article. CSPI urged that FDA not approve the petition as submitted.

CSPI stated that some of the treated groups in the first long-term rat study showed higher mortality than the controls and this increase was associated with chronic respiratory disease and cancers of lung lymphoid tissue. CSPI also claimed that the occurrence of pulmonary lymphoreticular tumors was relatively high in mid- and high-dose groups of both sexes and was "statistically significant" in high-dose females. The group also mentioned an earlier appearance of these tumors in mid- and high-dose males than in control and low-dose males.

The agency has evaluated this study comprehensively and, as outlined in the proceding Section, finds that deficiencies in the study prevent anyone from drawing any conclusions concerning treatment-related effects. For the reasons described above, the agency found no evidence of a neoplastic effect that is casually associated with acesulfame potassium from this study. Moreover, as noted above, the agency believes that the deficiencies in this study render it inadequate for assessing the carcinogenic potential of the test compound or for any other purposes of a safety evaluation. The second rat study is adequate however, for such purposes and forms a basis for the agency's final conclusion of safety.

On the second long-term rat study, CSPI stated "Although excess pulmonary tumors were not observed in this study, excess mammary gland tumors were found. According to the petitioner, the 'total incidence of mammary gland tumors in each of the test groups was about twice as high as in the controls * * *. In addition, malignant mammary tumors * * * were found only in test animals * * *.'" (Omissions made by CSPI)

The agency disagrees with CSPI's conclusion that this study is not adequate to demonstrate safety. FDA made a detailed evaluation based on the comprehensive reexamination of all the histological slides by the consulting pathologist (see preceding Section). As stated in the previous Section, fibroadenomas are common old-age tumors in female rats of this strain. The quotation of the petitioner's statement omits the fact that no mammary gland tumors were found in any of the male rats of this study. Based on the lack of dose response, the unusually low incidence of tumors in the concurrent control group compared with other contemporary controls, and the other reasons given in the previous Section, the agency concludes that there is no basis to find a causal relationship between acesulfame potassium treatment and development of mammary gland tumors.

In its letter to FDA, CSPI maintained that a positive dose response is not needed to reach a conclusion of carcinogenicity. The group also stated its belief that comparison with historical controls does not excuse the high tumor rates in either rat study. In this regard, they quote the Environmental Protection Agency's "Guidelines for Carcinogen Risk Assessment" as saying, "To evaluate carcinogenicity, the primary comparison is tumor response in dosed animals as compared with that in contemporary matched control animals" (September 24, 1986; 51 FR 33992 at 33995).

FDA disagrees with CSPI's interpretation of these guidelines. CSPI omitted from its quotation the sentences that follow it in the guidelines with respect to consideration of historical controls. The Environmental Protection Agency goes on to state, "Historical control data are often valuable, however, and could be used along with concurrent control data in the evaluation of carcinogenic responses * * *. The review of tumor data at sites with high spontaneous background requires special consideration * * *. For instance, a response that is significant with respect to the experimental control group may become questionable if the historical control data indicate that the experimental control group had an unusually low background incidence" (citations omitted).

FDA has long followed the principles stated in these guidelines, and in the Office of Science and Technology Policy, in reviewing the safety of food and color additives (November 2, 1982; 47 FR 49628 at 49629). The Office of Science and Technology Policy (March 14, 1985; 50 FR 10372 at 10418) stated:

> * * * With such data, the toxicologist may conclude that a study yielding statistical significance is not biologically significant or conversely that an effect is real, even though there is no "significant" difference between test and concurrence controls. Of 27 bioassay study reports issued by the NCI (National Cancer Institute) from 1978–1980, historical controls were used in 14 studies to show that an apparent increase of a specific tumor was not related to treatment. In 13 studies, the use of historical controls showed that an increase in tumors was related to treatment. Historical control data can be valuable when used appropriately, especially when the differences in incidence rates between treated and concurrent negative controls are small and can be shown to be within the anticipated historical incidence.

The agency points out that a determination of whether a compound is carcinogenic should be based on the overall weight of the evidence. The evidence can reasonably include a dose response or a lack of a dose response, consideration of historical controls, associated pathological data, the time to induction tumors, and the multiplicity of tumors. In the second long-term rat study, none of these factors lends weight to a finding of carcinogenicity (Ref. 6).

CSPI also questioned the results in a study the petitioners had volunteered which was conducted for 4 weeks with rats made diabetic by treatment with streptozotocin. CSPI stated that blood cholesterol levels were elevated 15 to 20 percent in groups of rats fed acesulfame potassium and suggested a relation to an increased risk of heart disease for diabetic humans who use this artificial sweetener.

FDA does not agree. The serum cholesterol levels were higher than the controls only in the low- and mid-dose groups but not in the high-dose group. These data do not show a dose-response relationship. In addition, differences in levels were relatively small and well within the normal cholesterol levels for rats (Ref. 7). FDA finds no relation between ingestion of the test compound and the levels of serum cholesterol in this study.

IV. Conclusions

FDA has evaluated the data in the petition and other relevant material and concludes that acesulfame potassium is safe under the conditions of use in a new 21 CFR 172.800 and that the regulations 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 21 CFR 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.

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 prepared under proposed 21 CFR 25.31(b) as published in the **Federal Register** of December 11, 1979 (44 FR 71742) may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Under FDA's current regulations implementing the National Environmental Policy Act (21 CFR Part 25), an action of this type would require an environmental assessment under § 25.31a(a).

V. Objections

Any person who will be adversely affected by this regulation may at any time on or before August 29, 1988 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 on 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. Kuznesof, P. M., Food and Color Additives Review Section, Memoranda of October 30, 1986, April 9, 1987, and August 5, 1987.

2. Cancer Assessment Committee, Memorandum of Conferences, November 21, 1983, February 21, 1985, December 12, 1985, and June 17, 1986.

3. Della Pora, G., L. Chieco-Bianchi, and N. Pennelli, "Tumors of the Haematopoietic System," *in* IARC Scientific Publications, No. 23, Vol. 2, "Tumors of the Mouse," p. 532, 1979.

4. Taylor, L. L., Additives Evaluation Branch, Memorandum of June 19, 1986.

5. Swaen, G. J. V., and P. Van Heerde, "Tumors of the Haematopoietic System," *in* IARC Scientific Publications, No. 5, Vol. 1, "Tumors of the Rat," Part 1, p. 187, 1973.

6. Hines, F. A., Diagnostic Pathology Branch, Memorandum of June 6, 1986.

7. Irausquin, H., Standards and Monitoring Branch, Memoranda of November 6, 1987, and October 20, 1982.

List of Subjects in 21 CFR Part 172

Food additives, Incorporation by reference.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, Part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR Part 172 continues to read as follows:

Authority: Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348); 21 CFR 5.10 and 5.61

2. A new § 172.800 is added to Subpart I to read as follows:

§ 172.800 Acesulfame potassium.

Acesulfame potassium (CAS Reg. No. 55589–62–3), also known as acesulfame K, may be safely used as a sweetening agent in food in accordance with the following prescribed conditions:

(a) Acesulfame potassium is the potassium salt of 6-methyl-1,2,3-oxathiazine-4(3*H*)-one-2,2-dioxide.

(b) The additive meets the following specifications:

(1) Purity is not less than 99 percent on a dry basis. The purity shall be determined by a method titled "Acesulfame Potassium Assay," which is incorporated by reference. Copies are available from the Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFF–330), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the **Federal Register**, 1100 L St. NW., Washington, DC 20408.

(2) Fluoride content is not more than 30 parts per million, as determined by method III of the Fluoride Limit Test of the Food Chemicals Codex, 3d Ed. (1981), p. 511, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.

(c) The additive may be used in the following foods when standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use:

(1) Dry, free-flowing sugar substitutes in package units not to exceed the sweetening equivalent of 2 teaspoonsful of sugar.

(2) Sugar substitute tablets.

(3) Chewing gum.

(4) Dry bases for beverages, instant coffee, and instant tea.

(5) Dry bases for gelatins, puddings, and pudding desserts.

(6) Dry bases for dairy product analogs.

(d) If the food containing the additive is represented to be for special dietary uses, it shall be labeled in compliance with Part 105 of this chapter.

(e) The additive shall be used in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect.

Dated: July 19, 1988.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 88-16972 Filed 7-27-88; 8:45 am]

BILLING CODE 4160-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 185 and 186

[OPP-00264; FRL-3422-1]

Tolerances for Pesticides in Food and Animal Feeds; Transfer of Regulations; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; correction.

SUMMARY: This document corrects a final rule that transferred former Parts 193 and 561 of Title 21 of the Code of Federal Regulations (CFR) regarding tolerances for pesticides in food and animal feeds into new Parts 185 and 186, respectively, of Title 40 of the CFR.

EFFECTIVE DATE: July 28, 1988.

FOR FURTHER INFORMATION CONTACT: John A. Richards, Chief, Federal Register Staff (TS-788B), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. NE-G009, 401 M St., SW., Washington, DC 20460, (202)-382-2253.

SUPPLEMENTARY INFORMATION: In FR Doc. 88-14718, published in the **Federal Register** of June 29, 1988 (53 FR 24666), EPA transferred former 21 CFR Parts 193 and 561 into new 40 CFR Parts 185 and 186, respectively. The following corrections are made to the document:

1. On page 24666, in the third column under the "old section-new section" table, in the entry for old section 193.80 change the new section entry from 185.375 to 185.410.

2. On page 24667, ir the first column, under the "old section-new section" table, in the entry for old section 193.470 change the new section entry from 185.5500 to 185.5550.

3. On page 24667, in the first column under the "old section-new section" table in the entry for old section 561.51 change the new section entry from 186.400 to 186.375.

4. On page 24667, in the first column, under the "old section-new section" table in the entry for old section 561.53 change the new section entry from 186.5050 to 186.4975.

5. On page 24667, in the first column, under the "old section-new section" table in the entry for old section 561.92 change the new section entry from 186.425 to 186.400.

PART 185—[CORRECTED]

6. On page 24667, in the third column, in the table of contents entry for section 185.375 1,1-Bis(*p*-chlorophenyl)-2,2,2-trichloroethanol, change the section number to 185.410 and reinsert the entry in numeric sequence.

PART 186—[CORRECTED]

7. On page 24668, in the third column, in the table of contents entry for section 186.400 Bentazon, change the section number to 186.375.

8. On page 24668, in the third column, in the table of contents entry for section 186.425 3,6-Bis(2-chlorophenyl)-1,2,4,5-tetrazine, change the section number to 186.400.

9. On page 24668, in the third column, in the table of contents entry for section 186.950, insert a hyphen after the first number 1 so that the entry reads "2-Chloro-1-(2,4,5-trichlorophenyl)vinyl dimethyl phosphate."

10. On page 24668, in the third column, in the table of contents entry for section 186.1850, remove the hyphen in the word "oxazolidine-dione" so that it reads "oxazolidinedione."

11. On page 26449, in the second column, in the table of contents entry for section 186.5050, change "Propenofos" to read "Profenofos" and change the section number to "186.4975" and reinsert the entry in numeric sequence.

(21 U.S.C. 348)

Dated: July 22, 1988.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 88-17105 Filed 7-27-88; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 271

[FRL-3420-9]

Georgia; Final Authorization of State Hazardous Waste Management Program

AGENCY: Environmental Protection Agency.

ACTION: Immediate final rule.

SUMMARY: Georgia has applied for final authorization of revisions to its hazardous waste program under the Resource Conservation and Recovery Act (RCRA). EPA has reviewed Georgia's application and has made a decision, subject to public review and comment, that Georgia's hazardous waste program revision for the hazardous components of radioactive mixed wastes and for the closure, post-closure and financial responsibility requirements satisfies all of the requirements necessary to qualify for final authorization. Thus, EPA intends to approve Georgia's hazardous waste program revision for the hazardous components of radioactive mixed wastes and for the closure, post-closure, and financial responsibility requirements. Georgia's application for program revision is available for public review and comment.

DATES: Final authorization for Georgia shall be effective September 26, 1988 unless EPA publishes a prior **Federal Register** action withdrawing this immediate final rule. All comments on Georgia's program revision application must be received by the close of business August 29, 1988.

ADDRESSES: Copies of Georgia's program revision application are available during 8:00 a.m.-4:00 p.m. at the following addresses for inspection and copying: Georgia Department of Natural Resources, Land Protection Branch, Room 1154, 205 Butler Street SE., Floyd Towers East, Atlanta, Georgia 30334, Phone: 404/656-2833; U.S. EPA Headquarters Library, PM 211A, 401 M Street SW., Washington, DC 20460, Phone: 202/382-5926; U.S. EPA Region IV, Library, 345 Courtland Street NE., Atlanta, Georgia 30365, Phone: 404/347-4216. Written comments on the application should be sent to Otis Johnson, at the address listed below.

FOR FURTHER INFORMATION CONTACT: Otis Johnson, Jr., Chief, Waste Planning Section, U.S. Environmental Protection Agency, 345 Courtland Street NE., Atlanta, Georgia 30365, Phone: 404/347-3016.

SUPPLEMENTARY INFORMATION:

A. Background

States with final authorization under section 3006(b) of the Resource Conservation and Recovery Act ("RCRA" or "the Act"), 42 U.S.C. 6929(b), have a continuing obligation to maintain a hazardous waste program that is equivalent to, consistent with, and no less stringent than the Federal hazardous waste program. In addition, as an interim measure, the Hazardous and Solid Waste Amendments of 1984 (Pub. L. 98–616, November 8, 1984, hereinafter "HSWA") allows States to revise their programs to become substantially equivalent instead of equivalent to RCRA requirements promulgated under HSWA authority. States exercising the latter option receive "interim authorization" for the HSWA requirements under section 3006(g) of RCRA, 42 U.S.C. 6926(g), and later apply for final authorization for the HSWA requirements. Georgia received final authorization for HSWA provisions contained in the July 15, 1985 Codification Rule, 50 FR 28702 on September 18, 1986.

Revisions to State hazardous waste programs are necessary when Federal or State statutory or regulatory authority is modified or when certain other changes occur. Most commonly, State program revisions are necessitated by changes to EPA's regulations in 40 CFR Parts 260–266 and 124 and 270.

B. Georgia

Georgia initially received final authorization on August 21, 1984. Georgia received authorization for revisions to its program on September 18, 1986. On December 31, 1987, Georgia submitted a program revision application for additional program approval for the hazardous components of radioactive mixed wastes and for the closure, post-closure, and financial responsibility requirements. Today, Georgia is seeking approval of its program revision in accordance with 40 CFR 271.21(b)(3).

EPA has reviewed Georgia's application, and has made an immediate final decision that Georgia's hazardous waste program revision satisfies all of the requirements necessary to qualify for final authorization. Consequently, EPA intends to grant final authorization for the additional program modifications to Georgia. The public may submit written comments on EPA's immediate final decision up until August 29, 1988. Copies of Georgia's application for program revisions are available for inspection and copying at the locations indicated in the "**ADDRESSES**" section of this notice

Approval of Georgia's program revision shall be come effective in 60 days unless an adverse comment pertaining to the State's revision discussed in this notice is received by the end of the comment period. If an adverse comment is received EPA will publish either (1) a withdrawal of the immediate final decision, or (2) a notice containing a response to comments which either affirms that the immediate final decision takes effect or reverses the decision.

Georgia is not seeking authorization to operate in Indian lands.

C. Decision

I conclude that Georgia's application for program revisions meets all of the statutory and regulatory requirements established by RCRA. Accordingly, Georgia is granted final authorization to operate its hazardous waste program as revised. Georgia now has reponsibility for permitting treatment, storage, and disposal facilities within its borders and carrying out other aspects of the RCRA-program, subject to the limitation of its revised program application and previously approved authorities. Georgia also has primary enforcement responsibilities, although EPA retains the right to conduct inspections under section 3007 of RCRA and to take enforcement actions under sections 3008, 3013 and 7003 of RCRA.

Compliance With Executive Order 12291

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Certification Under the Regulatory Flexibility Act

Pursuant to the provisions of 4 U.S.C. 605(b), I hereby certify that this authorization will not have a significant economic impact on a substantial number of small entities. This authorization effectively suspends the applicability of certain Federal regulations in favor of Georgia's program, thereby eliminating duplicative requirements for handlers of hazardous waste in the State. It does not impose any new burdens on small entities. This rule, therefore, does not require a regulatory flexibility analysis.

List of Subjects in 40 CFR Part 271

Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Indian lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control, Water supply.

Authority: This notice is issued under the authority of sections 2002(a), 3006 and 7004(b) of the Solid Waste Disposal Act as amended 42 U.S.C. 6912(a), 6926, 6974(b).

Lee A. Dehihns,

Acting Regional Administrator.

Dated: June 28, 1988.

[FR Doc. 88–17027 Filed 7–27–88; 8:45 am]

BILLING CODE 6560–50–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 424

[BERC–300–F]

Medicare Program; Indirect Part B Payment Procedure

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: Section 1842(b)(6) of the Social Security Act, as amended by section 2339 of the Deficit Reduction Act of 1984, authorizes a Medicare carrier to pay Medicare Part B benefits under certain circumstances directly to an entity that provides a health benefits plan complementary to Medicare and that pays the physician or supplier in full for the service. This rule sets forth the requirements these entities must meet to receive payment directly from Medicare.

EFFECTIVE DATE: August 29, 1988.

FOR FURTHER INFORMATION CONTACT: Ed Roth, 301–966–4486.

SUPPLEMENTARY INFORMATION:

Background

Under Medicare's Supplementary Medical Insurance program (Part B), the payment for the services of a physician or supplier is generally 80 percent of reasonable charges in excess of an annual deductible amount. Upon submission of a properly executed claim, this payment is made to the beneficiary, or alternatively to the physician or supplier if he or she accepts assignment of the claim.

Some beneficiaries have complementary insurance coverage that pays the annual deductible, the 20 percent coinsurance, and any amount by which the approved charge of the insurer exceeds the Medicare reasonable charge. In 1969 we established a procedure that allows a complementary insurance plan meeting certain conditions to pay a physician or supplier an amount that the physician or

supplier accepts as full payment for his services and then bill the Medicare carrier for the Part B payment that would otherwise be made to the beneficiary (42 CFR 405.1685).

Until July 1985, we limited the actual use of this procedure, under Medicare Carriers Manual instructions, to employment-related group insurance plans, group practice prepayment plans and HMOs, and, in the case of the latter two types of organizations, we made the procedure available only for limited types of services. Moreover, between May 1979 and July 1985, we prohibited carriers from accepting new applications by employment-related group insurance plans to use the procedure. In July 1985, we issued revised Medicare Carrier Manual instructions removing many of these limitations.

On July 1, 1986 (51 FR 23792), we proposed to amend § 405.1685, as well as other rules that have an impact upon this payment procedure, to implement section 1842(b) of the Act, as amended by section 2339 of the Deficit Reduction Act of 1984 (Pub. L. 98–369) commonly referred to as "DRA". Section 1842(b)(6) now provides the authority for carriers to pay Medicare Part B benefits, for services that are reimbursable on a reasonable charge or fee schedule basis, to entities that meet the conditions specified below, if the beneficiary has agreed in writing for payment to such an entity. The entity must be one that—

- Provides coverage of the services under a complementary health services plan as described above; and
- Has paid the physician or supplier an amount that includes the amount payable under Medicare and is accepted by the physician or supplier as full payment for the service.

Under the broad language of amended section 1842(b)(6) of the Act, any entity that meets the stated requirements can use the indirect payment procedure. This includes employers, unions, insurance companies, and retirement homes. It also includes prepayment organizations such as HMOs, competitive medical plans, and other prepaid plans, when they deal with a carrier rather than directly with HCFA.

The procedure is available only for services paid on a reasonable charge or fee schedule basis, and only when Medicare is primary payer. It is not available for services of providers or of other entitites that are paid under prospective payment or cost basis systems and is not available when Medicare is secondary payer.

The Act sets forth the indirect payment procedure as an alternative to Medicare payment to the beneficiary on the basis of an itemized bill or to the physician or supplier on the basis of an assignment. Indirect payment is available even for services furnished by a participating physician or supplier, that is, one that has agreed to accept assignments.

Section 1842(h)(1) of the Act, as amended by section 2306 of the DRA (and as further amended by section 9301(d)(2)(A)(ii) of Pub. L. 99–272), permits a participating physician or other supplier to accept payment under the indirect payment procedure in lieu of accepting Medicare assignment. Indirect payment is also available for clinicial diagnostic laboratory tests furnished by a physician or independent laboratory. Section 1833(h)(5)(C) of the Act, as amended by section 2303 of the DRA, permits a physician or independent laboratory to accept payment for clinical diagnostic laboratory tests under the indirect payment procedure in lieu of accepting Medicare assignment for those tests. Until December 22, 1987, when a physician or laboratory used this procedure for clinical diagnostic laboratory tests, Medicare payment for those tests was subject to deductible and coinsurance and was not 100 percent of the fee schedule amount or the actual charge (whichever is less) as it was when Medicare paid for the tests under assignment. This was changed by section 4085(i)(1) of the Omnibus Budget Reconciliation Act of 1987 Pub. L. 100–203), effective for services furnished on or after the date of enactment, December 22, 1987. Deductible and coinsurance no longer apply to clinical diagnostic laboratory tests for which payment is made under the indirect payment procedure.

Provisions of the Proposed Regulations

Since the amendments did not change the essential conditions for use of the procedure as set forth in the existing rules, we proposed primarily technical changes to conform the rules more closely to the language of the law, with minor revisions and clarifications. Specifically, we proposed to amend §§ 405.1672, 405.1679, 405.1685, and 405.1686, as discussed below.

A. Section 405.1672, Individual's Request For Direct Payment—General Provisions

A parenthetical statement at the end of § 405.1672(c) indicated that "for payment to organizations that pay bills on behalf of enrollees, see § 405.1685." In line with proposed changes in § 405.1685 discussed below, we proposed to change this statement to read: "For payment to entities that pay for services on behalf of entitled individuals, see § 405.1685."

B. Section 405.1679, Execution of Claim For Payment

This section made no reference to the indirect payment procedure. It discussed who could execute a claim for an individual. We proposed to add a new paragraph (e) to clarify that an entity that provides complementary health insurance and meets the requirements of the indirect payment procedure could execute a claim on behalf of the beneficiary under that procedure. The beneficiary would authorize the entity to receive his or her Part B payments. Section 1842(b)(3)(B) of the Act (following clause (ii)), requires that a Part B bill be submitted in such form as is provided by regulations. Section 1835(a)(1) of the Act requires (in the case of services furnished by certain "providers of services") that the beneficiary submit a written request for payment "except in cases in which the Secretary finds it impracticable for the beneficiary to do so". Since the main purpose of the indirect payment procedure is to simplify the billing process, for beneficiaries and for physicians and other suppliers, and since the beneficiary must give written authorization for the complementary coverage plan to receive the Part B payments, we believe that a request for payment signed by the beneficiary, or a written statement authorizing the plan to submit claims on his or her behalf, is unnecessary.

C. Section 405.1685, Payment to Organizations That Pay Bills on Behalf of Enrollees.

We proposed to change the title of this section to "The indirect payment procedure." All the proposed special requirements for payment under the indirect payment procedure would be set forth in the revised § 405.1685(a). We proposed that Medicare Part B payment for the services of a physician or supplier otherwise payable to a beneficiary or to his or her legal representative or representative payee could be made to an entity that provides coverage to the beneficiary under a complementary health benefits plan. (This was to make it clear that payment under the indirect payment procedure is an exception to the rule that benefits that are not assigned to the physician or supplier must be paid to the beneficiary or to his or her legal representative or representative payee.) Paragraphs (a)(1) through (a)(6) and (b), discussed below, would specify the requirements the entity must meet to receive the payment.

To improve technical accuracy, we also proposed to change references

throughout paragraphs (a) and (b) from "organization" to "entity," and from "bills" to "services."

Any entity using the indirect payment procedure would have to meet the general criterion set forth in a new § 405.1685(a)(1). This provision provided explanatory language to indicate that the plan would have to be complementary to Medicare, in line with current practice.

In paragraph (a)(2) of the proposed regulations we proposed to continue the current requirement that the entity must have made full payment to the person furnishing the service. Editorial changes were to be made to follow the language of the law more closely.

In paragraph (a)(3), we proposed to clarify the role of an "authorized representative" of a beneficiary in executing an agreement for Medicare Part B payment to the entity. (We proposed also to revise § 405.1672(c) to provide that any of the persons specified in § 405.1679 could execute a claim on behalf of the beneficiary.)

We proposed to redesignate current paragraph (a)(3) as paragraph (a)(4) and revise it editorially, and to combine the contents of the current paragraphs (a)(4) and (a)(5) in paragraph (a)(5), requiring that the entity submit any information the carrier needs to meet requirements of the Medicare program.

In paragraph (a)(6) we proposed to require an entity to have in place a process that would identify and exclude from its requests for payment all services for which Medicare is the secondary payer. This is called for by the provision that the entity may request payment only in cases in which it pays for the service under a plan complementary to Part B. Section 1862(b) of the Act and 42 CFR 405.316–405.329 indicate when Medicare is secondary payer.

Paragraph (b) of § 405.1685 indicated that the entity could choose not to pay and claim reimbursement for all Part B bills on behalf of a beneficiary; the entity could establish criteria to determine at its discretion which bills it would pay. We proposed to revise the paragraph to show that the entity has discretion to determine which services, rather than which bills, it will pay. In addition, to prevent possible double billing (when the entity and the beneficiary bill the carrier for the same service), we proposed to require that the entity undertake to cover, and to pay and claim reimbursement for, either one or more well defined general categories of services, or all Part B services.

D. Section 405.1686, Organizations Qualified To Receive Payment on Behalf of Enrollee

This section described the types of organizations that could qualify to receive payment under the indirect payment procedure. Since the availability of the indirect payment procedure no longer would be limited to the types of organizations specified in § 405.1686, we proposed to delete this section.

Response to Comments

We received timely comments from a Medicare carrier, a State Medicaid Agency, and a private health benefits plan on the proposed regulations. Because there were so few comments and because each commenter's comments are so distinct from the others, we discuss them individually.

The carrier raised a number of issues regarding the administration of the indirect payment provision. These questions and our responses are as follows:

Question: Will the carrier be required to make programming changes to make deductible and coinsurance applicable to the charges for clinical diagnostic laboratory tests furnished by independent laboratories?

Response: Carriers should not make these programming changes. Under section 4085(i)(1) of the Omnibus Budget Reconciliation Act of 1987, the Part B deductible and coinsurance no longer apply to charges for clinical diagnostic laboratory tests for which payment is made under the indirect payment procedure.

Question: Will there be carrier involvement to ascertain that an entity using the indirect payment procedure meets the requirements of the final regulations?

Response: Yes. The entity will submit its request to use the procedure to the carrier to which it expects to submit the most claims. The carrier will determine whether the entity meets the requirements and notify HCFA.

Question: What mechanism will be developed to inform the carrier of the status of the entity?

Response: HCFA will add the entity to a list of approved entities in the Medicare Carriers Manual and assign it a national identification number ("approval number") to show on its claim.

Question: How will the carrier determine whether or not a private insurance plan should receive Medicare reimbursement, since the plan might be obligated by its terms to pay for the service in full regardless of Medicare?

Response: In applying to use the indirect payment procedure, the entity must agree to claim payment for a service only when it covers the service under a plan complementary to Medicare Part B and meets the requirements for reimbursement for that service. Medicare beneficiaries who are members of the plan receive from the carrier an explanation of medical benefits detailing the services Medicare paid for and we anticipate that they would soon complain to the carrier or HCFA if Medicare payment is made to a plan for services for which the plan is obligated to pay in full regardless of Medicare.

The State Medicaid agency's comment on the regulations and our response are as follows:

Comment: The State Medicaid agency provides payment for medical services as a payer of benefits complementary to Medicare. In addition, the agency covers only the amount by which a Part B payment falls short of the charge approved for the service or the State's fee, whichever is less. Accordingly, the agency believes it should be considered an entity entitled to use the indirect payment procedure.

Response: While State Medicaid plans are similar in some respects to health benefits plans complementary to Medicare, we do not regard them as such plans for purposes of using the indirect payment procedure. Unlike private insurance plans, State Medicaid plans generally pay fees lower than the fees usually charged in the community. Under the indirect payment procedure, the amount the entity pays the physician or supplier for a service goes into his customary charge profile. If this amount is less than his usual charges, the physician's payment level may be penalized. The indirect payment procedure is designed for use by entities that pay physicians' and suppliers' usual charges.

Moreover, State agencies generally pay no more than (if as much as) the Medicare approved charge. There is no disadvantage, therefore, to a physician or supplier who participates in Medicaid in accepting Medicare assignments and submitting Medicare claims directly to the Medicare carrier. State agencies have procedures for obtaining Medicare claims information for purposes of making the supplementary Medicaid payment on these claims. Thus, it would merely create an administrative complication for the Medicare program to authorize the use of the indirect payment procedure by States.

The health benefits plan made a number of comments objecting to the

prohibition in the proposed regulations against the imposition of any copayment in connection with the indirect payment procedure. These comments and our responses to them are as follows:

Comment: There is no prohibition in the statute against imposing a copayment.

Response: While it is true that the prohibition is not stated explicitly in the statute, it is the most supportable interpretation of that part of section 1842(b)(6) of the Act that requires a physician (or supplier) to accept the plan payment as full payment. This part of the statutory language could mean either: (1) That the plan must be the entire ultimate source of payment for the service (exclusive of Medicare Part B); or (2) that the plan must merely be the entire immediate source of payment. The first interpretation would prohibit the billing of a copayment by either the plan or the physician; the second would merely prohibit the billing of a copayment by the physician. The first interpretation is more consistent with the objectives of the legislation that we stated in our recommendation that legislation in this area be initiated. In recommending the indirect payment provision to Congress, we stated that the provision should be designed to permit the physician to submit a single claim, relieve the beneficiary of any need to file a claim, and protect the beneficiary against any financial liability for the service, if Medicare and the plan together fully cover the services.

We believe that Congress fully agreed with out recommendation and did not contemplate the collection of a copayment by a plan under the indirect payment procedure. Congress did not provide guidance in the statute or in the legislative committee reports on determining the permissible amount of any copayment.

Comment: Prohibiting a copayment limits the availability of the indirect payment procedure and disadvantages carrier-dealing health benefits plans relative to HMOs that enter into contracts with HCFA and may impose copayments.

Response: In the case of a health benefits plan that uses the indirect payment procedure (unlike a health benefits plan that has a contract with HCFA as an HMO or competitive medical plan), we do not regulate the amount of premiums the plan may charge. For a plan that pays physicians on a fee-for-service basis, this makes the indirect payment procedure an attractive alternative to entering into a risk-capitation contract with HCFA (i.e., a contract under which HCFA pays the plan, as an HMO or competitive medical plan, a capitation rate with the plan assuming the financial risk of providing services covered under Part A or Part B of Medicare). Permitting the imposition of a copayment would make the indirect payment procedure an even more attractive alternative to a risk-capitation contract if the plan believes that a copayment would help it to reduce utilization and other costs. Making the indirect payment procedure this attractive, however, conflicts with our initiative encouraging plans to enter into risk-capitation contracts. We find little basis for permitting such a disincentive to risk capitation contracts without an explicit statutory requirement to do so.

Comment: This prohibition precludes use of a copayment as a utilization control mechanism.

Reponse: Copayments are certainly one form of utilization control. However, other control exist, such as careful review of claims, partial refund of premiums to plan members, etc. The indirect payment procedure was basically intended for Medigap plans that ordinarily do not charge a copayment and that assume full responsibility for the difference between the Medicare payment and the approved charge of the plan.

Final Rule

While the final rule was under development, HCFA undertook to redesignate all rules on conditions for Medicare payment (including Subpart P of Part 405) as a new Part 424. Accordingly, the section numbers of Part 424 are substituted in the final rule, as shown in the following discussion.

We are adopting the proposed rule as final without substantive changes. For clarity and precision we are making the following editorial revisions in § 405.1685, which is now § 424.66:

1. Provide a more descriptive heading;

2. Revise paragraph (a)(6) to require that the entity "identify and exclude from its requests for payment all services for which Medicare is secondary payer * * *." (The wording of the proposed rule appeared to emphasize the process leading to identification rather than exclusion as such.)

3. Clarify (in paragraph (b)) that an entity that does not pay and claim reimbursement for all Part B services must establish in advance precise criteria for determining the services for which it will pay.

Language in the proposed rule was misleading.

By referring to "cover" and "pay and claim reimbursement for" in the same sentence, we created the erroneous impression that the entity must pay and claim reimbursement for any service that it covers. Actually, an entity's health benefit plans might have copayment requirements or approved charge limitations that would prevent it from claiming reimbursement for some services. Also, an entity might choose to use the indirect payment procedure for some of its plans but not others.

By stating that an entity must determine which well-defined categories of services for which it would pay, we created the erroneous impression that there are HCFA-defined categories from which the entity can choose.

The paragraph (e) that we proposed to add to § 405.1679, redesignated as § 424.36, under which an entity authorized to use the indirect payment procedure could execute a claim on behalf of the beneficiary, appears in the final rule as paragraph (d).

Other proposed changes to § 405.1672 (paragraphs (c) and (d)) became inappropriate or unnecessary as we simplified our rules in a final rule published March 2, 1988 (53 FR 6629). The content of these paragraphs is found in new § 424.34(a) and § 424.54. In that regard, paragraph (a) of new § 424.66, which includes the content of former § 405.1686 is being removed, as we proposed and as it is inconsistent with current law.

Regulatory Impact Statement

A. Executive Order 12291

Executive Order (E.O.) 12291 requires us to prepare and publish a final regulatory impact analysis for any final regulation that meets one of the E.O. criteria for a "major rule"; that is, that would be likely to result in: An annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or, significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. While this rule may result in administrative savings because it will permit the physician or supplier to file a single claim and receive payment in a single check, the overall effect will be negligible. Coverage and payment amounts will not be affected. Therefore, because no threshold criteria under E.O. 12291 will be exceeded, this rule is not considered a major rule and an impact analysis is not required.

B. Regulatory Flexibility Act

We generally prepare a final regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), unless the Secretary certifies that a final regulation will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, States and individuals are not small entites, but we treat all physicians or suppliers as small entities. While, in some cases, physicians or suppliers may benefit slightly because a single claim will be permitted for a given service, the overall impact on the physician or supplier will be minimal.

For these reasons, we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities, and we have therefore not prepared a regulatory flexibility analysis.

C. Paperwork Reduction Act

These changes will not impose paperwork collection requirements. Consequently, they need not be reviewed by the Executive Office of Management and Budget (EOMB) under the authority of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Nursing homes, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 424

Administrative practice and procedure, Conditions for payment, Medicare claims, Physician certification, Plan of treatment, Request for payment.

42 CFR Part 424 is amended as set forth below:

PART 424—[AMENDED]

1. The authority citation continues to read as follows:

Authority: Secs. 216(j), 1102, 1814, 1815(c), 1935, 1842(b), 1861, 1866(d), 1870 (e) and (f), 1871, and 1872 of the Social Security Act (42 U.S.C. 416(j), 1302, 1395f, 1395g, 1395n, 1395u, 1395x, 1395cc, 1395gg, 1395hh, and 1395ii).

2. Section 424.36 is amended to redesignate paragraph (d) as (e) and add a new paragraph (d) to read as follows:

§ 424.36 Signature requirements.

* * * * *

(d) *Claims by entities that provide coverage complementary to Medicare.* A claim by an entity that provides coverage complementary to Medicare Part B may be signed by the entity on the beneficiary's behalf.

(e) *Acceptance of other signatures for good cause.* * * *

3. Section 424.60 is amended by revising paragraph (a) to read as follows:

§ 424.60 Scope.

(a) This subpart sets forth provisions applicable to payment after the beneficiary's death and payment to entities that provide coverage complementary to Medicare Part B.

* * * * *

4. Section 424.66 is amended to revise the section heading, remove paragraphs (a) and (b), redesignate paragraph (c) as (a) and revise it, and add a new paragraph (b). As amended, § 424.66 reads as follows:

§ 424.66 Payment to entities that provide coverage complementary to Medicare Part B.

(a) *Conditions for payment.* Medicare may pay an entity for Part B services furnished by a physician or other supplier if the entity meets all of the following requirements:

(1) Provides coverage of the service under a complementary health benefit plan (this is, the coverage that the plan provides is complementary to Medicare benefits and covers only the amount by which the Part B payment falls short of the approved charge for the service under the plan).

(2) Has paid the person who provided the service an amount (including the amount payable under the Medicare program) that the person accepts as full payment.

(3) Has the written authorization of the beneficiary (or of a person authorized to sign claims on his behalf under § 405.1679) to receive the Part B payment for the services for which the entity pays.

(4) Relieves the beneficiary of liability for payment for the service and will not seek any reimbursement from the beneficiary, his or her survivors or estate.

(5) Submits any information HCFA or the carrier may request, including an itemized physician or supplier bill, in order to apply the requirements under the Medicare program.

(6) Identifies and excludes from its requests for payment all services for which Medicare is the secondary payer.

(b) *Services paid by the entity.* An entity is not required to pay and claim reimbursement for all Part B services furnished to members of its plans. However, if it does not pay and claim reimbursement for all those services, it must establish in advance precise criteria for identifying the services for which it will pay and claim reimbursement.

(Catalog of Fedral Domestic Assistance Program No. 13.774, Medicare—Supplementary Medical Insurance)

Dated: August 18, 1988.

William L. Roper,

Administrator, Health Care Financing Administration.

Approved: June 10, 1988.

Otis R. Bowen,

Secretary.

[FR Doc. 88-16995 Filed 7-27-88 8:45 am]

BILLING CODE 4120-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA-6931]

Changes in Flood Elevation Determinations; Arkansas et al.

AGENCY: Federal Emergency Management Agency.

ACTION: Interim rule.

SUMMARY: This rule lists those communities where modification of the base (100-year) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base (100-year) elevations for new buildings and their contents and for second layer insurance on existing buildings and their contents.

DATES: These modified elevations are currently in effect and amend the Flood Insurance Rate Map (FIRM) in effect prior to this determination. From the date of the second publication of notice of these changes in a prominent local newspaper, any person has ninety (90) days in which he can request through the community that the Administrator, reconsider the changes. These modified elevations may be changed during the 90-day period.

ADDRESSES: The modified base (100-year) flood elevation determinations are available for inspection at the office of the Chief Executive Officer of the community, listed in the fifth column of the table. Send comments to that address also.

FOR FURTHER INFORMATION CONTACT: Mr. John L. Matticks, Chief, Risk Studies Division, Federal Insurance