Reports Clearance Officer, on one of the following numbers:

PHS: 202–245–2100
HCFA: 301–594–8650
FSA: 202–245–0652

Written comments and recommendations for the proposed information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, Room 3208, Washington, DC 20503.

ATTN: (name of OMB Desk Officer).

Dated: June 29, 1987.

James F. Trickett,

Deputy Assistant Secretary, Administrative and Management Services.

[FR Doc. 87–15040 Filed 7–1–87; 8:45 am]

BILLING CODE 4150–04–M

Food and Drug Administration

[Docket No. 86P–0172]

New Animal Drug Status of Injectable Products Containing Amino Acids

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing this notice pursuant to a court-ordered consent decree. This publication will formally notify TechAmerica Group, Inc. (TechAmerica), 15th and Oak Sts., Elwood, KS 66024, and all other interested persons, that TechAmerica's Aminoplex Solution and Aminoplex-C, and other similar injectable products which contain amino acid compounds, are new animal drugs that require an approved new animal drug application before they may be distributed in interstate commerce.

EFFECTIVE DATE: July 2, 1987.

ADDRESS: Information contained in Docket Number 86P–0172, and made a part of this notice by reference, may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Andrew J. Beaulieu, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3044.

SUPPLEMENTARY INFORMATION: On July 26, 1984, a complaint for forfeiture (Civil No. 3–84–1049, U.S. District Court for the District of Minnesota, Third Division) against various quantities of Aminoplex Solution and Aminoplex–C (Aminoplex) was filed. The complaint alleged that the substances in question were adulterated and misbranded drugs in violation of 21 U.S.C. 351(a)(5) and 21 U.S.C. 352(f)(1). TechAmerica intervened as claimant to the seized articles, and entered into a consent decree on February 27, 1986.

The consent decree provided, among other things, that TechAmerica could, pursuant to 21 CFR 10.30, file a citizen petition regarding the distribution of Aminoplex. The consent decree also specifically provides that:

> From and after the publication of FDA's response to the citizen petition . . . or within six months following the entry of this decree, whichever occurs later, claimant shall alter its distribution of Aminoplex to conform to the terms of FDA's response to the citizen petition, including the cessation of all distribution, if that is required. This applies even if claimant is in the process of pursuing further legal remedies.

Pursuant to the consent decree, TechAmerica filed a citizen petition dated April 14, 1986. As provided for in the consent decree, FDA is publishing below its response to the citizen petition filed by TechAmerica.

Citizen Petition Response

This is in response to your citizen petition, dated April 14, 1986, requesting the Commissioner of Food and Drugs to classify Aminoplex solution and Aminoplex C solution (hereinafter "Aminoplex") as a veterinary food, or alternatively, as a generally recognized as safe and effective drug which may be labeled with adequate directions for use. Presently, the Aminoplex label has been revised pursuant to an out-of-court settlement of previous litigation. The revisions include deleting indications for animal species other than cattle, and deleting directions for use other than intravenously. The product contains amino acids, minerals, vitamins, dextrose, and electrolytes.

I. Aminoplex is Not Food

A. *Historically,* amino acids, minerals, vitamins, dextrose, and electrolyte products, singly or in combinations, intended as injectables have been regarded as drugs by the medical profession, by FDA, and by the regulated industry for more than 40 years. To our knowledge TechAmerica Group has not challenged this concept until now.

There are numerous citations from the published scientific literature to support the history of drug status of injectable nutrients; for example:

1. *Clinical Nutrition Update,* a report of the Symposium on Clinical Nutrition Update: Amino Acids, March 3–4, 1977, Denver, Colorado, sponsored by the American Medical Association and the American Academy of Pediatrics, p. 215, "Many nutrient preparations are in fact drugs and are regulated accordingly, e.g., injectable nutrients.", in left column last paragraph. Page 217 describes the investigations conducted by a major large volume parenteral manufacturer to obtain marketing approval for a new amino acid solution (and p. 225).

2. *The United States Pharmacopeia,* which lists drugs, from at least 1962 (p. 601) to 1985, has listed Protein Hydrolysate Injection (1985 Ed., p. 911) as a sterile solution of amino acids and short-chain peptides, a product in many ways similar to Aminoplex. Thus, Aminoplex fits in principale at least, the definition of a drug in 201(g)(1)(A) of the Food, Drug, and Cosmetic Act ("articles recognized in the official United States Pharmacopeia").

3. The purpose of both old and new texts is to demostrate the period of consistency. Various texts on pharmacology and therapeutics describe and discuss articles composed of injectable amino acids. (Pharmacology may be defined simply as the science of drugs, therapeutics the art of applying drugs in disease.) An article which is discussed in such texts is generally regarded as a drug. Discussions of injectable amino acids appear in texts such as *Pharmacology and Therapeutics* by Arthur Grollman, Lea & Febiger 1954, p. 778, and the *Pharmacological Basis of Therapeutics,* Gilman et al, Macmillan 7th Ed. 1985, p. 859.

Further, the (American Medical Association) *AMA Drug Evaluations 1st Ed.* 1971, p. 122 similary discusses and evaluates such articles as drug, as do current editions.

4. The status of Aminoplex as a drug is further supported by the long-standing unchallenged policy of FDA as reported in Trade Correspondence in Vol. 1, Kleinfeld, Dunn and Kaplan, *Judicial Record 1938–1964,* which discloses in TC2–A–Nov. 1945 a letter which discusses the use of amino acids in foods and drugs. This letter reiterated the agency policy (more than 40 years ago) that "Amino acid preparations offered for parenteral use fall in the category of New Drugs" (p. 749).

B. Historically, food is commonly consumed, taken into the body by mouth, not by injection. The only reason to inject nutrients parenterally would be to cure, mitigate, treat or prevent nutritional or other disease in man or other animals.

Judge Sofaer, in the Starch Blocker case, said, "Congress appears to have intended that this component [the parenthetical exclusion of food in section 201(g)(1)(c) of the act] of the statutory definition of "food" refer to *common usage* . . ." [Emphasis added]. *American Health Products.* v. *Hayes* 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983), food is defined in section 201(f)(1) as "articles used for food or drink . . ." The "common usage" standard argues convincingly against considering injectable nutrients as "food," because injection is not a common usage of food.

C. *Claims.* A previously marketed product with the same name bore the indication, "An aid in the supportive treatment of debilitated large animals." No formualtion or lable change can alter the fact that Tech America once advertised a nearly identical product as a medicinal compound.

The use of the word "treatment" relates the product directly to drug status. Dorland's *Medical Dictionary,* 26th Ed., defines

treatment as "the management and care of a patient for the purpose of combatting disease or disorder," which in this case may be a deficiency of the active ingredients from any cause, whether malnutrition, infection, disfunction, or disorder of body functions.

Thus, section 201(g)(1)(C) of the act is also applicable. As stated above, parenthetical phrase, "(other than food)", has no importance here.

Conclusion

Aminoplex is a drug.

Status as New Animal Drug

Effectiveness

A new animal drug is a drug product which is not generally recognized as safe and effective for its intended purpose. (Section 201(w) of the act.) The Supreme Court has held that ". . . the hurdle of 'general recognition' of effectiveness requires at least the 'substantial evidence' of effectiveness that would be needed for approval of an NDA. In the absence of any evidence of adequate and well-controlled investigations supporting the efficacy of [the drug product] *a fortiori* [the drug product] would be a 'new drug' subject to the provisions of the Act." (Weinberger vs. Hynson, Westcott and Dunning, Inc., 93 S. Ct 2469 (1973) at 630.) The definition of new animal drug in Section 201(w) is even more extensive. Also, the meaning of "substantial evidence" is delineated in Section 512(d)(3) of the act.

None of the following material submitted with the petition constitutes substantial evidence of effectiveness of Aminoplex as evidenced by the following review of literature accompanying the petition:

1. Broderick, G.A., Satter, L.D., and Harper, A.E. Use of Plasma Amino Acid Concentration to Identify Limiting Amino Acids for Milk Production. Journal of Dairy Science, Vol. 57, pages 1015–1023, year 1974.

The hypothesis that essential amino acids will not accumulate in blood plasma unless supplied in excess of requirement was the basis for an attempt by the authors to determine those essential amino acids most likely to limit lactation. The authors measured plasma essential amino acid concentrations, milk production, and milk components as oral protein intake increased by increments from inadequate to adequate amounts. The authors felt that from their experiment that the amino acids valine and lysine may be co-limiting with methionine to suggest that these three amino acids may be nearly equally inadequate for milk production synthesis.

2. Chew, B.P., Eisenman, J.R., and Tanaka, T.S. Arginine Infusion Stimulates Prolactin, Growth Hormone, Insulin, and Subsequent Lactation in Pregnant Dairy Cows. Journal of Dairy Science, Vol. 67, pages 2507–2518, year 1983.

The authors studied the effects of daily intravenous infusions of arginine on changes in serum of various hormones (prolactin, growth hormone, and insulin) in pregnant dairy cows and the effect of changes of these hormones on subsequent lactation. Arginine induced increases in these above-mentioned hormones and urea nitrogen, and the changes of these serum contents were associated with increased milk yield subsequent to calving.

3. Foldager, J., Huber, J.T., and Bergen, W.G. Factors Affecting Amino Acids in Blood of Dairy Cows. Journal of Dairy Science, Vol. 63, pages 396–404.

The authors evaluated the influence of protein percent and source, time after calving, and milk yield on concentrations of amino acids in plasma of dairy cows fed different sources and percents of crude protein. They also studied those amino acids which might limit milk synthesis in diets varying in protein and nonprotein nitrogen.

4. Hogan, J.R., Weston, R.H., and Lindsay, J.R. Influence of Protein Digestion on Plasma Amino Acid Levels in Sheep. Aust. J. Biol. Sci. Vol. 21, pages 1263–1275, year 1968.

The authors conducted a study to determine whether the levels of amino acids in the plasma of sheep were related to the amounts of protein digested in the intestines. Infusions per abomasum of calcium caseinate were utilized in the experiment.

5. Kung, L., Jr., Huber, J.T., Bergen, W.G. and Petitclerc, D. Amino Acids in Plasma and Duodenal Digesta and Plasma Growth Hormone in Cows Fed Varying Amounts of Protein of Differing Degradability. Journal of Dairy Science, vol. 67, pages 2519–2524, year 1984.

According to the authors, the intent of their study was to extend the information on feeding increased protein, heat-treated soybean meal, and ammonia-treated corn silage to lactating dairy cows. They made the following noteworthy statement to their readers, "Interpretation of plasma essential amino acids should be with caution because the most limiting essential amino acids for milk production often cannot be verified from plasma essential amino acids alone." These same authors also acknowledged, "Essential and branched chain amino acids in plasma increased as protein and amount of protected protein in the diet increased. These changes were accompanied by decreased concentrations of nonessential amino acids."

6. Leibholz, J. The Effect of Starvation and Low Nitrogen Intakes on the Concentration of Free Amino Acids in the Blood Plasma and on the Nitrogen Metabolism in Sheep. Aust. J. Agric. Res., vol. 21, pages 723–734, year 1970.

In this study, sheep were administered a low nitrogen diet or starved for 12 or 20 days to determine the effect of very low nitrogen intake and starvation on the concentrations of free amino acids in plasma of sheep. Also in this same study, the author evaluated the effect of the treatments on the sheep's nitrogen balance and the saliva and rumen nitrogen concentrations observed. The author stated in her discussion, "Under field conditions low nitrogen intakes are frequently encountered, and it is often difficult to assess the need for a nitrogen supplement."

7. Oldham, J.D. Amino Acid Requirements for Lactation in High Yielding Dairy Cows. Chapter 3 in: Recent Advances in Animal Nutrition, edited by W. Haresign, pp. 33–65, Cambridge University Press, year 1980.

The subject of amino acid requirements and utilization for high-yielding dairy cows has been discussed.

In his conclusion, the author states, in part, that there is a case for looking afresh at the role of dietary protein for manipulating intake in the high yielding dairy cow, and particular amino acids may have a role in this respect. The author also notes that ". . . the chance of an economic return from amino acid supplementation would not, at present, seem to be very strong from the point of view of meeting an amino acid deficiency in conventional terms."

8. Owens, F.N. and Bergen, W.G. Nitrogen Metabolism of Ruminant Animals: Historical Perspective, Current Understanding and Future Implications. Journal of Animal Science, vol. 57, Suppl. 2, pages 498–518, year 1983.

An extensive review is provided on the importance of ruminal microbes as a protein source; nutritive quality of microbial protein; ruminal ammonia and nitrogen recycling; nonprotein nitrogen utilization, sources and blood levels; amino acid metabolism; essential amino acid requirements; nitrogen requirements; limits on microbial protein synthesis; protein degradation in the rumen; postruminal digestion and absorption of nitrogen compounds; nitrogen digestibility and retention-classical studies; utilization of amino acids after absorption; role of hormones and additives on nitrogen metabolism and growth; descriptive models for whole animal nitrogen metabolism.

9. Phillips, L.S. Nutrition, Somatomedins, and the Brain. Metabolism, vol. 35, pages 78–87, year 1986.

A review is presented on the relationship between nutrition, insulin, hormone, and brain components (pituitary and hypothalamic mechanisms).

10. Powanda, M.C. Host Metabolic Alterations During Inflammatory Stress as Related to Nutritional Status. American Journal of Veterinary Research, vol. 41, pages 1905–1911, year 1980.

Host metabolic sequelae to inflammatory stress (such as microbial infections, parasitism, endotoxemia, etc.) as related to nutritional status are discussed. The author reviews some of the metabolic alterations which occur in a host during infection as to the mechanisms which initiate them and the role these metabolic alterations may have in host defense and repair processes.

11. Richardson, C.R. and Hatfield, E.E. The Limiting Amino Acids in Growing Cattle. Journal of Animal Science, vol. 46, pages 740–745, year 1978.

The authors conducted a series of experimental studies to determine the first, second, and third-limiting amino acids in the microbial protein of growing cattle as indicated by nitrogen retention and plasma amino acid concentrations. Abomasal infusions of amino acids and semipurified diets essentially protein free were utilized in the various experimental procedures involving growing steers.

12. Sawin, C.T. Hormonal Control of Daily Energy Supply, in: The Hormones: Endocrine Physiology, pages 255–265. Little Brown and Company, Boston, year 1969.

Hormonal controls involving processes of eating, post-eating, fasting, exercise, and other stresses (such as cold, surgery, etc.) are discussed. The author's discussion is general and does not point out variations, differences, etc. between the various species.

13. Schwab, C.G., Satter, L.D., and Clay, A.B. Response of Lactating Dairy Cows to Abomasal Infusion of Amino Acids. Journal of Dairy Science, vol. 59, pages 1254–1270, year 1976.

The authors conducted a series of five experiments in which single or mixtures of amino acids were infused into the abomasum of lactating dairy cattle. The authors' intent was to determine if the quality of protein passing from the rumen could be improved for milk, milk fat, or milk protein production and to further determine the most limiting amino acids and their sequence of limitation. In part, the authors noted "Because of the differences in feed proteins with respect to amino acid composition and the extent of their degradation in the rumen, ingredient composition of the ration will influence which amino acids are most limiting for milk production and/or milk protein synthesis."

14. Stein, T.P., Leskiw, M.J., Wallace, H.W., and Oram-Smith, J.C. Changes in Protein Synthesis after Trauma: Importance of Nutrition. American Journal of Physiology, vol. 233, pages E–348–E–355, year 1977.

The authors conducted trauma studies, using laboratory rats, to evaluate the clinical situations in which experimental animals were given different parenterally administered nutrient formulations (Diet I containing amino acids and glucose, Diet II containing only amino acids, Diet III of severely hypocaloric glucose, and Diet IV of the same amount of glucose as Diet I but without the amino acids. For the fifth formulation-Diet V, the rats were given Diet I pre-trauma, and immediately after trauma the diet was changed to diet III). The authors concluded from their experiments with such laboratory rat models that amino acids become limiting before energy posttrauma and that the requirement is mostly for amino acid nitrogen posttrauma.

These citations make no reference to the use of Aminoplex solution and/or Aminoplex C solution. Furthermore, they do not support petitioner's claim that Aminoplex solution and/or Aminoplex C solution is a veterinary food or alternatively a generally recognized safe and effective drug which may be labeled with adequate directions for use by lay persons.

15. Mangan, J.L. and Wright, P.C. Plasma Concentrations of Free Amino Acids in Sheep in Relation to Time of Feeding and Protein Intake. Proc. Nutr. Soc., vol. 32, pages 52A–53A, year 1973.

The authors noted that in sheep most essential amino acids in blood plasma decrease in concentration as the protein intake of the diet decreased.

16. Nimrick, K., Hatfield, E.E., Kaminski, J., and Owens, F.N. Quantitative Assessment of Supplemental Amino Acid Needs for Growing Lambs Fed Urea as the Sole Nitrogen Source. J. Nutrition, vol. 100, pages 1301–1306, year 1970.

The authors undertook a quantitative assessment of the supplemental needs for amino acid requirements of growing lambs fed urea as the sole nitrogen source. They also studied the relationship of plasma amino acid concentrations to nitrogen balance. The treatments consisted of graded levels of L-amino acids infused abomasally. The authors acknowledged, "Plasma amino acid concentrations are difficult to interpret since many variables affect them."

These nutritional studies make no reference to the use of Aminoplex solution and/or Aminoplex C solution. The papers do not support petitioners's claim that Aminoplex solution and/or Aminoplex C solution is a veterinary food or alternatively a generally recognized safe and effective drug which may be labeled with adequate directions for use by lay persons.

17. National Research Council. Ruminant Nitogen Usage. National Academy Press. Chapter entitled Nitrogen Metabolism in Tissues, pp. 57–65, year 1985.

The Subcommittee on Nitrogen Usage in Ruminants of the Committee on Animal Nutrition furnishes an updated review on (1) amino acid metabolism and (2) protein requirements in the ruminant species

Under "amino acid metabolism," the following subtopics are discussed: free amino acid pools, utilization of amino acids, protein synthesis, synthesis of nonprotein compounds, amino acid oxidation, and nitrogen excretion. Detailed remarks under the heading of "protein requirements" are divided into requirements for maintenance and requirements for tissue growth, lactation, and pregnancy.

The Subcommittee acknowledges, "Although there is interest and considerable specultation about amino acid requirements of ruminants, there is limited information on amino acid requirements of ruminant species."

This nutritional citation makes no reference to the use of Aminoplex solution and/or Aminoplex C solution.

This NRC publication does not support petitioner's claim that Aminoplex solution and/or Aminoplex C solution is a veterinary food or alternatively a generally recognized safe and effective drug which may be labeled with adequate directions for use by lay persons.

None of the above cited articles is a report of a controlled study of Aminoplex. Indeed, none of the articles ever mentions Aminoplex. Hence, taken together or separately, they cannot constitute substantial evidence of Aminoplex effectiveness.

As defined by the Act, "substantial evidence" means evidence consisting of adequate and well-controlled investigations. The essential elements of adequate and well-controled studies are found in 21 CFR 514.111(a)(5)(ii) of the new animal drug regulations.

Thus, in the absence of any submitted evidence of adequate and well-controlled investigations supporting the effectiveness of Aminoplex, following the courts reasoning, *a fortiori* Aminoplex is a new animal drug.

Safety

Based on the information submitted by TechAmerica (which did *not* include safety studies of Aminoplex) and other data before FDA, there is insufficient information to determine whether Aminoplex is safe for its intended uses.

In considering the "safety" of Aminoplex, we have examined our files and the scientific literature. True, FDA has received no adverse drug reaction reprots following the use of Aminoplex. However, this does not mean that no adverse reactions have *occurred*, just that none have been reported to FDA. Because Aminoplex is not an approved drug, there is no requirement that TechAmerica report complaints or adverse reactions.

However, FDA *has* received reports of adverse reactions from the use of similar drugs in horses.

Textbooks state that parenteral nutrients may cause hyperglycemia, glycosuria, osmotic diuresis and dehydration depending upon the rate of administration. Too large an amount of any of the amino acids causes an imbalance, resulting in abnormally high serum levels and an increased amino aciduria. There is also the risk of the development of hyperammonaemia.

Similarly, imbalance of the electrolytes may produce toxicity or deficiencies.

(References: *AMA Drug Evaluations 1983, Hazards of Intravenous Feeding,* I.D.A. Johnson, *Adverse Drug Reaction Bulletin,* No. 77, August 1979, pp. 276–279, *Meyler's Side Effect of Drugs,* An Encyclopedia of Adverse Reactions and Interactions, 9 ED, pp. 577–586, Excerpta Medica, Amsterdam 1980, *Vet. Pharm & Therap, 5 Ed.,* Booth, N.H. and MacDonald, LE, 1982.)

Compliance Policy Guide 7125.31

The petitioner alleges that Compliance Policy Guide 7125.31 provided the basis for the "new animal drug" charges and, therefore, constitutes a rule established outside the requirements of the Administrative Procedure Act. The Agency rejects this argument on the grounds that the Guide, as in the case of any Compliance Policy Guide, is not in itself a basis for regulatory action. The Agency issues compliance policy guides to inform its headquarters and field personnel to provide general or specific limits of whether a product, process, or condition is in compliance with relevant laws and regulations. It is not a rule within the meaning of the APA or 21 CFR 10.85. The complaint in the seizure action did not allege violation of the Compliance Policy Guide, but, rather, violations of the Federal Food, Drug, and Cosmetic Act.

Additional Comments on the Petition

1. None of the scientific articles submitted with the petition consist of adequate and well-controlled reports of investigations conducted with Aminoplex for the purpose of developing data to support the safe and effective use of Aminoplex.

To the contrary, several claims, using other similar products or considering such products generically, beneficially to affect inappetance which which may result from stress and other causes thus supporting the therapeutic or preventive intent, either directly or by implication, further strengthening the status of Aminoplex as a drug.

2. GRAS status of substances, 21 CFR 582.1, clearly states restrictions, notably several references to "use in food", handling "as a food ingredient", "would generally be regarded as safe for the purpose intended," and closes with the statement, ". . . will not affect its status for other use not specified.

. . ." Therefore, we conclude the GRAS status of ingredients of Aminoplex, which we have determined to be an injectable drug, is irrelevant. Indeed, many of the part 582 regulations cited in the petition close with the phrase ". . . when used in accordance with good manufacturing or feeding practice."

3. The petition states without further explanation, "Humans ingest nutrient supplements largely as tablets and capsules; that route of administration in cattle is obviously impractical." Yet most drugs and nutrient supplements are administered orally, and owners of cattle and veterinarians will attest that it is much easier, convenient and cheaper to administer them this way than intravenously.

For the reasons discussed above, your petition is denied.

Sincerely yours,

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

* * * * *

Pursuant to the Federal Food, Drug, and Cosmetic Act, FDA considers all injectably-administered amino acid compounds—such as Aminoplex—to be new animal drugs which require FDA approval prior to their manufacture and distribution. The agency's position is clearly supported by the information provided in response to TechAmerica's citizen petition. Pursuant to the terms of the consent decree, TechAmerica is hereby notified to cease distributing Aminoplex and any similar amino acid products. Injectable products containing amino acid compounds marketed by other firms are subject to regulatory action by FDA unless approved new animal drug applications are in effect for such products.

Dated: June 25, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87-14989 Filed 7-1-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87F-0183]

Ciba-Geigy Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba-Geigy Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of tris(2,4-di-*tert*-butylphenyl) phosphite as an antioxidant and thermal stabilizer for poly(methylpentene) polymer intended to contact food.

FOR FURTHER INFORMATION CONTACT: Andrew D. Laumbach, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 7B3999) has been filed by Ciba-Geigy Corp., Three Skyline Dr., Hawthorne, NY 10532, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of tris(2,4-di-*tert*-butylphenyl) phosphite as an antioxidant and thermal stabilizer for poly(methylpentene) polymer intended to contact food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: June 23, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-14990 Filed 7-1-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87P-0176]

Canned Pacific Salmon Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Kelley-Clarke, Inc., to market test canned skinless and boneless chunk salmon packed in water and containing sodium tripolyphosphate to inhibit protein curd formation during retorting. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the food.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than September 30, 1987.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF-414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-485-0110.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Kelley-Clarke, Inc., Seattle, WA 98199.

The permit covers limited interstate marketing tests of canned skinless and boneless chunk salmon packed in water. The test product deviates from the standard of identity for canned Pacific salmon (21 CFR 161.170) is four ways: (1) The form of pack is chunk, i.e., not less than 50 percent of the drained weight of the salmon is retained on a ½-inch mesh screen; (2) the skin and backbone, i. e., vertebrae and associated bones (neural spines and ventral ribs), are removed; (3) water, in an amount not to exceed 10 percent of the water capacity of the can, will be used as a packing medium and to aid in dispersion of salt; and (4) sodium tripolyphosphate, in an amount not to exceed 0.50 percent of the weight of the finished food including free liquid, will be used to inhibit formation of protein curd during retorting. The test product meets all requirements of § 161.170 with the exception of these deviations. The permit provides for the temporary marketing of 120,000 cases of test product containing twenty-four 6½-ounce cans each. The test product will be distributed throughout the United States.

The test product is to be manufactured at the Petersburg Fisheries plant located in Petersburg, AK 99833.

Each of the ingredients used in the food is stated on the label as required by the applicable sections of 21 CFR Part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than September 30, 1987.

Dated: June 23, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87-14991 Filed 7-1-87; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 87P-0178]

Canned Pacific Salmon Deviating From Identity Standard; Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit has been issued to Peter Pan Seafoods, Inc., to market test canned skinless and boneless chunk salmon packed in water and containing sodium tripolyphosphate to inhibit protein curd formation during retorting. The purpose of the temporary permit is to allow the applicant to measure consumer acceptance of the food.

DATES: This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than September 30, 1987.

FOR FURTHER INFORMATION CONTACT: Karen L. Carson, Center for Food Safety and Applied Nutrition (HFF–414), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0110.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 130.17 concerning temporary permits to facilitate market testing of foods deviating from the requirements of the standards of identity promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341), FDA is giving notice that a temporary permit has been issued to Peter Pan Seafoods, Inc., Seattle, WA 98121.

The permit covers limited interstate marketing tests of canned skinless and boneless chunk salmon packed in water. The test product deviates from the standard of identity for canned Pacific salmon (21 CFR 161.170) in four ways: (1) The form of pack is chunk, i.e., not less than 50 percent of the drained weight of the salmon is retained on a ½-inch mesh screen; (2) the skin and backbone, i.e., vertebrae and associated bones (neural spines and ventral ribs) are removed; (3) water, in an amount not to exceed 10 percent of the water capacity of the can, will be used as a packing medium and to aid in dispersion of salt; and (4) sodium tripolyphosphate, in an amount not to exceed 0.50 percent of the weight of the finished food including free liquid, will be used to inhibit formation of protein curd during retorting. The test product meets all requirements of § 161.170 with the exception of these deviations. The permit provides for the temporary marketing of 200,000 cases of test product containing twenty-four 6½-ounce cans each. The test product will be distributed throughout the United States.

The test product is to be manufactured at the Petersburg Fisheries plant located in Petersburg, AK 99833.

Each of the ingredients used in the food is stated on the label as required by the applicable sections of 21 CFR Part 101. This permit is effective for 15 months, beginning on the date the food is introduced or caused to be introduced into interstate commerce, but no later than September 30, 1987.

Dated: June 23, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87–14992 Filed 7–1–87; 8:45 am]

BILLING CODE 4160-01-M

Office of Human Development Services

Availability of Funds; Child Development Associate Scholarship Assistance Program

AGENCY: Head Start Bureau (HSB), Administration for Children, Youth and Families (ACYF), Office of Human Development Services, (OHDS), Department of Health and Human Services (HHS).

ACTION: Announcement of the availability of funds for grants to States for child development associate scholarship assistance under Title VI of the Human Services Reauthorization Act of 1986, Pub. L. 99–425.

SUMMARY: FY 1987 funds are available for grants to States (including eligible territories and insular areas) to enable them to award scholarships to eligible individuals who are candidates for the Child Development Associate (CDA) national credential. The sholarship would assist in the payment of the fee for the assessment done by the CDA credentialing organization, the Council for Early Childhood Professional Recognition (CECPR), a subsidiary of the National Association for the Education of Young Children (NAEYC). This Announcement sets forth the application process and requirements for these grants.

DATE: Application must be received by August 31, 1987.

ADDRESS: Applications to: Clennie H. Murphy, Jr., Acting Associate Commissioner, Head Start Bureau, P.O. Box 1182, Washington, DC 20013.

FOR FURTHER INFORMATION CONTACT: Hector Sanchez, Program Specialist, Head Start Bureau, P.O. Box 1182, Washington, DC 20013, (202) 755–7710.

SUPPLEMENTARY INFORMATION:

Introduction

Title VI of the Human Services Reauthorization Act of 1986, Pub. L. 99–425, makes available $1,000,000 for FY 1987 grants to States to enable them to award scholarships to eligible individuals who are candidates for the Child Development Associate (CDA) national credential. Only those States (and territories and insular areas) which receive a grant under Title XX of the Social Security Act are eligible to apply for scholarship grants.

The Governor of each State must designate a State agency or other agency or organziation to administer this program.

State allocations which are listed below have been computed according to a State's total population. A $1,073.00 minimum, however, has been established for each territory and insular area. This minimum is based on the cost of three scholarships at $325.00 each, plus 10 percent allowed for State administrative costs.

Not more than 10 percent of the funds received by a State may be used for costs of administering this program.

The funds allocated to States which do not apply will be reallocated to those States which have submitted approvable applications.

All FY 1987 funds must be expended by September 30, 1989.

Scholarship assistance must be awarded only to eligible individuals; on the basis of the financial need of such individuals; and in amounts sufficient to cover the cost of application, assessment, and credentialing for the CDA credential for such individuals. This means that no costs of education or training leading to CDA candidacy may be funded.

The term "eligible individual" is defined in the statute as a candidate for the CDA credential whose income does not exceed the poverty line, as defined in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)) by more than 50 percent. (See Appendix I for the FY 1987 Poverty Income Guidelines.)

Some of the tasks of the designated agency include:

- Establishing a process for publicizing the availability and the criteria for awarding these funds throughout the State;
- Soliciting applications from eligible individuals who meet the financial eligibility requirements and who are CDA candidates.
- Establishing procedures for awarding scholarships to cover the fees for registration, assessment and credentialing;
- Establishing review criteria and a procedure for review of applications to assure that eligible individuals are selected from diverse child care settings

to include both privately and publicly funded programs.

Additional Information Regarding the CDA Credential

The number of infants, toddlers and 4- and 5-year-old children in group programs mulitiplied dramatically in recent years in Head Start, day care, public school kindergartens, pre-kindergartens and many other privately and publicly-funded child care and child development settings.

Statistics indicate that over half (54.4 percent) of all mothers with children under age six are working and it is estimated that the number of working mothers will continue to grow. The fastest growing segment of the work force are mothers of infants. Fifty-one percent of mothers with children under the age of three now work full-time, compared to 30 percent in 1970. Additionally, 80 percent of the women presently in the work force are of childbearing age, and an estimated 93 percent of this group will become pregnant during their working career.

According to some studies, more preschool children are now cared for outside the home than in it. Families place great trust in the staff of these programs because the daily performance of the teacher or caregiver determines the qualitly of the child's preschool experiences.

In 1971, the CDA program was initiated to improve the skills of caregivers in center-based, family day care, and home visitor programs and to give recognition to persons who have skill and knowledge levels by granting a CDA credential. These are individuals who have applied for and successfully completed the CDA assessment process. (See Appendix II for a description of the CDA program and the CDA Assessment System.)

Child Development Associates are skilled caregivers who have shown their ability to work with either or both of the following age groups: Birth through three or three through five and their families. Some are center-based caregivers; others are family day care providers; and still others are home visitors. They work in Head Start, day care, or other preschool programs. An optional bilingual specialization is available to CDA candidates working in bilingual (Spanish/English) programs.

More than 19,000 child care providers have earned the CDA credential since 1975, and 32 States have incorporated a requirement for the CDA credential in their child care licensing requirements. Since October 1986 the Employment and Training Administration of the Department of Labor has been working with the Administration for Children, Youth and Families (ACYF) through its local Private Industry Council (PICs) to make Job Training Partnership Act (JTPA) funds available for professional development culminating in the CDA credential.

The national CDA program is administered by the Council for Early Childhood Professional Recognition, a subsidiary of the National Association for the Education of Young Children. The Council is located at 1718 Connecticut Avenue NW., 5th Floor, Washington, DC 20009. The toll free number is 800–424–4310.

Application Requirements

The application requirements for these grants do not go beyond the requirements in the statute and 45 CFR Part 74. Each requirement has been cited to the specific section of the law.

The application may be submitted in any format as long as it contains all requirements specified.

The application must be signed by the Chief Executive of the State and must contain the following information and assurances:

1. The name of the agency or other organization designated by the Governor to administer the CDA Scholarship program (Part 74).

This may include the designated Title XX agency, the State day care licensing authority, a college or university, or other agency or organization (section 603(a)).

2. The agency's Employee Identification Number (EIN).

3. The name, address, and telephone number of the administrator of this program and a contact person, if different (section 603(a)).

4. The following assurances:

a. Scholarships will be awarded only to eligible individuals and only on the basis of the financial need of such individuals (section 603(b));

b. Scholarships will be awarded in amounts sufficient to cover the cost of application, assessment, and CDA credentialing for such individuals (section 603(b));

c. Scholarships will be made available for candidates applying for family day care, center-based and the home visitor CDA credential (Conference Report 99–815);

d. Not more than 10 percent of the funds received will be used for administering this program within the State (section 603(b));

e. In awarding scholarship funds, ensure that the needs of rural and urban areas are appropriately addressed (section 603(c));

f. The State will annually report to the Secretary information on the number of eligible individuals assisted under this grant program and their positions and salaries before and after receiving the CDA credential (section 605(a)).

Notification Under Executive Order 12372

This program is covered under Executive Order 12372.

"Intergovernmental Review of Federal Programs," for State plan consolidation and simplification only (45 CFR 100.12). The review and comment provisions of the Executive Order and Part 100 do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (Pub. L. 96–511), the application requirements contained in this Notice have been submitted to the Office of Management and Budget for approval.

State Allocations: Child Development Scholarship Program

FY 87 Allotment

Alabama	16,648
Alaska	2,086
American, Samoa	1,073
Arizona	12,738
Arkansas	9,801
California	88,992
Colorado	13,260
Connecticut	13,160
Delaware	2,558
Dist. of Columbia	2,599
Federated States of Micronesia	1,073
Florida	45,795
Georgia	24,354
Guam	1,073
Hawaii	4,335
Idaho	4,177
Illinois	48,029
Indiana	22,940
Iowa	12,142
Kansas	10,172
Kentucky	15,534
Louisiana	18,617
Maine	4,823
Marshall Islands	1,073
Maryland	18,146
Massachusetts	24,192
Michigan	37,865
Minnesota	17,366
Mississippi	10,840
Missouri	20,895
Montana	3,438
Nebraska	6,701
Nevada	3,801
New Hampshire	4,076
New Jersey	31,356
New Mexico	5,942
New York	79,714
North Carolina	25,723
North Dakota	2,862
Northern Mariana	1,073

Ohio	44,862
Oklahoma	13,761
Oregon	11,157
Pennsylvania	49,656
Puerto Rico	13,606
Republic of Palau	1,073
Rhode Island	4,014
South Carolina	13,769
South Dakota	2,946
Tennessee	19,681
Texas	72,431
Utah	6,893
Vermont	2,211
Virgin Island	1,073
Virginai	23,516
Washington	18,146
West Virginia	8,145
Wisconsin	19,886
Wyoming	2,132
Total	$1,000,000

Dated: March 31, 1987.

Dodie Livingston,

Commissioner, Administration for Children, Youth and Families.

Dated: May 21, 1987.

Jean K. Elder,

Assistant Secretary for Human Development Services-Designate.

Appendix I—FY 1987 Poverty Income Guidelines

Appendix II—The CDA Program and Assessment System

Appendix I

1986 POVERTY INCOME GUIDELINES FOR ALL STATES (EXCEPT ALASKA AND HAWAII) AND THE DISTRICT OF COLUMBIA

Size of family unit	Poverty guideline
1	$5,360
2	7,240
3	9,120
4	11,000
5	12,880
6	14,760
7	16,640
8	18,520

For family units with more than 8 members, add $1,880 for each additional member.

POVERTY INCOME GUIDELINES FOR ALASKA

Size of family unit	Poverty guideline
1	$6,700
2	9,050
3	11,400
4	13,750
5	16,100
6	18,450
7	20,800
8	23,150

For family units with more than 8 members, add $2,350 for each additional member.

POVERTY INCOME GUIDELINES FOR HAWAII

Size of family unit	Poverty guideline
1	$6,170
2	8,330
3	10,490
4	12,650
5	14,810
6	16,970
7	19,130
8	21,290

For family units with more than 8 members, add $2,160 for each additional member.

Appendix II

The CDA Program

The goal of the CDA program is to meet the dramatic need for quality child care. The CDA Competency Standards are the core of the CDA program. They are a statement of the skills needed to be a competent caregiver. CDA training programs are designed to train persons to acquire those skills. In CDA assessment and credentialing, the Competency Standards are the basis upon which caregivers are assessed. However, it is important to understand that, although CDA training programs and the CDA assessment system are both based on the Competency Standards, the training programs and the assessment system are separate from each other. All Candidates for the CDA Credential must apply for and successful complete the CDA assessment process.

The CADA Competency Standards

The CDA Competency Standards define the skills needed by center-based child care staff, family day care providers, and home visitors. Carefully developed by the early childhood profession, the standards set the criteria for a caregiver's performance with children and their families.

A competent caregiver meets the needs of children and their families. The CDA Competency Goals are to: maintain a safe and healthy learning environment, promote the physical and intellectual development of children, provide opportunities for children to develop a positive feeling about themselves as individuals and in a group, encourage positive relationships with families, work cooperatively with other staff, and demonstrate a professional commitment. These six Competency Goals are divided into 13 Functional Areas which define more specifically the functions that a competent caregiver msut perform (see the accompanying chart).

Child Development Associate Competency Standards

This chart outlines the Definition of a CDA, the Competency Goals, and the Functional Areas. It describes the settings for CDA assessment as well as the Infant/Toddler Endorsement, Preschool Endorsement, and Bilingual Specialization.

Official Definition of The CDA

The Child Development Associate or CDA is a person who is able to meet the specific needs of children and who, with parents and other adults, works to nurture children's physical, social, emotional and intellectual growth in a child development framework. The CDA conducts herself or himself in an ethical manner.

The CDA has demonstrated competence in the goals listed below through her or his work in one of the following settings.

1. In a center-based program (CDA–CB).
2. In a home visitor program (CDA–HV).
3. In a family day care program (CDA–FDC).

Within a center-based setting, a person who demonstrates competence working with children from birth to three is a Child Development Associate with an Infant/Toddler Endorsement; or,

A person who demonstrates competence working with children aged three through five is a Child Development Associate with a Preschool Endorsement.

Within any of the above settings, a person who works in a bilingual program and has demonstrated bilingual competence is a Child Development Associate with a Bilingual Specialization.

Competency Goals	Functional Areas, Key Words
I: To establish and maintain a safe, healthy learning environment.	1. Safe. 2. Healthy. 3. Learning environment.
II: To advance physical and intellectual competence.	4. Physical. 5. Cognitive. 6. Communication. 7. Creative.
III: To support social and emotional development and provide postive guidance.	8. Self. 9. Social. 10. Guidance.

CDA Training

CDA training programs give child care workers one opportunity to learn the CDA Competencies. There are many different kinds of CDA training programs offered by a variety of institutions, including colleges, universities, and vocational schools. Some of the training programs specialize

in preparing persons to work in bilingual/bicultural child care settings.

Students in CDA training programs do not automatically receive the CDA Credential. Furthermore, a person does not have to take part in CDA training to be eligible for the credential. Candidates for the credential may be involved in other types of formal training or be informally trained through workshops and seminars. The only way to gain the CDA Credential is to apply to the CDA National Credentialing Program and successfully complete the assessment process.

The CDA Assessment System

The CDA assessment and credentialing system is one way staff can demonstrate skills acquired through various forms of training and experience. Individual skills are assessed, with direction given for further improvement. The assessment process is based on the caregiver's ability to demonstrate the CDA Competencies while working with children, families, and staff.

CDA assessment and credentialing is currently available to caregivers working with children ages birth through five in center-based care, as home visitors, and in family day care homes. Those who successfully demonstrate their ability are awarded the CDA Credential. A Child Development Associate has met a national standard for quality child care.

Those working in bilingual/bicultural child car settings may find much to gain by applying for the CDA Credential with a Bilingual Specialization. The Bilingual specialization is an expansion of the existing credential. It acknowledges the unique skills required to work in bilingual child care settings. This credential is available only for Spanish/English languages at the present time.

The preceding has given an overview of the CDA program. Detailed materials may be obtained from the Council for Early Childhood Professional Recognition, 1718 Connecticut Avenue NW., Washington, DC 20009.

CDA Assessment System

Eligibility for the CDA Credential center-based

To be eligible for CDA assessment in a center-based setting, a person must meet each of the following criteria—

1. Be 18 years old or older.

2. Identify a state-approved [1] child development which has at least ten children enrolled or at least two caregivers where she/he can be observed by other persons while working as a primary caregiver. For the preschool endorsement, the caregiver must be observed working with a group of at least eight children, the majority of whom must be three through five years old. For the infant/toddler endorsement, the caregiver must be observed working with a group of at least three children under the age of three.

3. Have had either some formal training (for example, in a university, college, junior college, vocational/technical school, or high school) or some informal training (for example, workshops, seminars, or inservice training) in early childhood education or child development, or, for the infant/toddler endorsement, training in infant/toddler education. In total, a person must have had at least three educational experiences. Each workshop or course equals one educational experience.

4. Have had at least 640 hours of experience within the last five years working with children in a group, ages birth to three for the infant/toddler endorsement or three to five for the preschool endorsement.

5. Be able to speak, read and write well enough to understand and be understood by both children and adults.

There are two additional requirements for the CDA Credential with a Bilingual Specialization. Candidates for the Bilingual Specialization must—

6. Be able to speak, read, and write both English and Spanish well enough to understand and be understood by both children and adults; and

7. Have access to a child development center where both languages and cultures are consistently used in all daily activities.

Eligibility for the CDA Credential home visitor.

To be eligible for CDA assessment as a home visitor, a person must meet each of the following criteria—

1. Be 18 years old or older.

2. Identify a program where she/he can be observed conducting home visits during which the focal child of the parent is five years old or younger. Home visits must be used by the program as the primary method of delivery on a continuing basis throughout the year.

3. Have had either some formal training (for example, in a university, college, junior college, vocational/technical school, or high school) or some informal training (for example, workshops, seminars, or inservice training) in child development, infant development, or parenting. In total, a person must have had at least three educational experiences. Each workshop or course equals one educational experience.

4. Have had at least 480 contact hours of experience within the last five years working with families in home visitor settings; she/he must have worked with a minimum of four families on a continuous basis where the focal child was five years old or younger, and

5. Be able to speak, read, and write well enough to understand and be understood by both children and adults.

There are two additional requirements for the CDA Credential with a Bilingual Specialization. Candidates for the Bilingual Specialization must—

6. Be able to speak, read, and write both English and Spanish well enough to understand and be understood by both children and adults; and

7. Have access to a home visitor program that fosters bilingual development and in which both languages and cultures are consistently used in all daily activities.

Eligibility for the CDA Credential family day care.

To be eligible for CDA assessment in a family day care setting, a person must meet each of the following criteria—

1. Be 18 years old or older.

2. Identify a state-approved [2] program where she/he can be observed by other persons while working as a primary caregiver with at least two children five years old or younger who are not related to the caregiver.

3. Have had either some formal training (for example, in a university, college, junior college, vocational/technical school, or high school), or some informal training (for example, USDA Child Care Food Program workshops or Family Day Care Association training sessions) in early childhood education or child development. In total, a person must have had at least three educational experiences. Each workshop or course equals one educational experience.

4. Have had at least 640 contact hours as a family day care provider over a minimum period of ten months.

There are two additional requirements for the CDA Credential with a Bilingual Specialization. Candidates for the Bilingual Specialization must—

5. Be able to speak, read, and write both English and Spanish well enough to understand and be understood by both children and adults; and

[1] Persons should seek clarification from the CDA National Credentialing Program if they work in a state where there is no state licensing or approval mechanism for their center.

[2] Persons should seek clarification from the CDA National Credentialing Program if they work in a state where there is no state licensing or approval mechanism for their center.

6. Have access to a family day care setting that fosters bilingual development and in which both languages and cultures are consistently used in all daily activities.

The Assessment Process

The assessment is conducted by a four member Local Assessment Team, or LAT. Each member has an important role.

1. The Candidate. A full member of the LAT, the Candidate has an equal voice in assessing her/his own competence.

The Candidate compiles evidence to demonstrate competence in the 13 Functional Areas. This compiled material is in the form of a Portfolio. (Information on putting together the Portfolio will be supplied by the CDA National Credentialing Program after one applies.)

2. The Advisor. This member of the LAT is selected by the Candidate. The Advisor is an early childhood professional who may be a college professor, a CDA trainer, a CDA, a center director, or someone else. The Advisor establishes a professional relationship with the Candidate over time, observes the Candidate's performance, provides assistance and feedback, and helps the Candidate decide when to be assessed.

The Parent/Community Representative (P/C Rep). Also selected by the Candidate, the P/C Rep must be or have been a parent or guardian of a child five years old or younger. The P/C Rep must have been recently involved with the Candidate's program as a parent or volunteer, but must not be a current employee. Furthermore, the P/C Rep must not have a child currently in the Candidate's care. The P/C Rep serves as the spokesperson on the LAT for the parents and the community. To do this, the P/C Rep gets questionnaires filled out by the parents of children in the Candidate's care and observes the Candidate working with the children and their families.

4. The CDA Representative (CDA Rep). Assigned by the CDA National Credentialing Program, the CDA Rep is a professional in early childhood education who has worked with young children in a child development setting. The CDA Rep has been trained to observe, interview, make fair judgments, and verify that procedures are followed. The CDA Rep observes the Candidate, and participates in the LAT meetings at which the Candidate's competence is assessed.

The Local Assessment Team (LAT) Meeting

Each of the four team members collects information about the Candidate's skills in working with young children. After the information is gathered, the team members attend the LAT meeting. The LAT reviews the materials that have been compiled, examines the Candidate's performance in each of the 13 Functional Areas, and decides if the Candidate has met the CDA Competency Standards. For bilingual assessments, the LAT also looks for demonstrated skill in the use of both languages. Each team member has equal importance in judging the Candidate's competence. This means that the Candidate participates fully in the process. At the completion of the meeting, the LAT votes on the Candidate's overall competence. The LAT may recommend that the Candidate be awarded the CDA Credential or it may decide that the Candidate needs more training. In order to recommend that the Candidate receive the CDA Credential, however, all team members must agree that the Candidate is competent.

The CDA Representative sends all the meeting materials to the CDA National Credentialing Program for review and verification. Depending on how the LAT voted, the Candidate is then either awarded the CDA Credential or advised to seek more training.

How Long It Takes

The assessment system is designed for Candidates to progress at their own pace. Some take longer than others. Much depends on how fast the Candidates, and those with whom they work, can collect the information needed for assessment. The important thing is that assessments should not take place until Candidates feel they are ready.

Cost to the Candidate

The total cost for a CDA assessment and Credential is $325. Two separate fees are paid, as follows:

$25.00 registration fee;

$300.00 assessment and credentialing fee.

These fees are in effect through August, 1987. For further information on current CDA Candidate fees, please contact the CDA National Credentialing Program (800) 424–4310 or (202) 265–9090.

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Public Health Service

Statement of Organization, Functions, and Delegations of Authority, Food and Drug Administration

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organizations, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, as amended most recently in pertinent part at 49 FR 45263 of November 15, 1984) is amended to reflect realignment from ten Regional Offices to six.

Section HF-B, Organization and Functions is amended as follows:

1. Delete paragraph (f–4) *Regional Field Offices (HFR1-HFRX)* and their Appendix HR–1 in its entirety; and

2. Insert new paragraph (f–4) *Regional Field Offices (HFR).*

(f–4) *Regional Field Offices (HFRN, HFRA, HFRS, HFRM, HFRW, HFRP).* Field operations for the enforcement of the laws under the jurisdiction of FDA are carried out by six Regional Field Offices identified as follows:

Region	Regional field office	Area of responsibility
Northeast Region (HFRN)	New York, NY	Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, New York.
Mid-Atlantic Region (HFRA)	Philadelphia, PA	Pennsylvania, New Jersey, Delaware, Maryland, Virginia, West Virginia, Ohio, Kentucky.
Southeast Region	Atlanta, GA	North Carolina, South Carolina, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Puerto Rico.
Midwest Region (HFRM)	Chicago, IL	Michigan, Indiana, Illinois, Wisconsin, Minnesota, North Dakota, South Dakota.
Southwest Region (HFRW)	Dallas, TX	Texas, Arkansas, Oklahoma, Missouri, Kansas, Iowa, Nebraska, New Mexico, Colorado, Utah, Wyoming.
Pacific Region (HFRP)	San Francisco, CA	Alaska, Hawaii, Arizona, California, Nevada, Idaho, Montana, Oregon, Washington.

The Regional Field Office is the primary organizational component for each region and is organized into district offices, divisions, and/or specialized centers. A Regional Field Office is under the direction of a Regional Food and Drug Director who is the primary executive of the agency within the region. The Regional Food and Drug