

**Vessels: RENAISSANCE TWO and
RFNAISSANCE THREE**

Dated: July 23, 1990.

Joseph C. Polking,
Secretary.

[FR Doc. 90-17593 Filed 7-27-90; 8:45 am]
BILLING CODE 6730-01-M

**Security for the Protection of the
Public Financial Responsibility To
Meet Liability Incurred for Death or
Injury to Passengers or Other Persons
on Voyages; Issuance of Certificate
(Casualty)**

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility to Meet Liability Incurred for Death or Injury to Passengers or Other Persons on Voyages pursuant to the provisions of section 2, Public Law 89-777 (46 U.S.C. 817(d)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Renaissance Cruises, Inc., Yachtship
Holding Corporation and Yacht Ship
Italy 2 Srl., P.O. Box 350307, 1800 Eller
Drive, #300, Fort Lauderdale, Florida
33335-0307.

**Vessels: RENAISSANCE TWO and
RENAISSANCE THREE**

Dated: July 23, 1990.

Joseph C. Polking,
Secretary.

[FR Doc. 90-17595 Filed 7-27-90; 8:45 am]
BILLING CODE 6730-01-M

**Security for the Protection of the
Public Indemnification of Passengers
for Nonperformance of
Transportation; Issuance of Certificate
(Performance)**

Notice is hereby given that the following have been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of section 3, Public Law 89-777 (46 U.S.C. 817(e)) and the Federal Maritime Commission's implementing regulations at 46 CFR part 540, as amended:

Royal Caribbean Cruises Ltd., 903 South
America Way, Miami, Florida 33132.

Vessel: MAJESTY OF THE SEAS

Dated: July 24, 1990.

Joseph C. Polking,
Secretary.

[FR Doc. 90-17594 Filed 7-27-90; 8:45 am]
BILLING CODE 6730-01-M

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**

Food and Drug Administration

[Docket No. 88N-0319]

**Blood Collection Kits Labeled for
Human Immunodeficiency Virus (HIV-
1) Antibody Testing; Availability of a
Letter for Interested Persons**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a letter, dated April 18, 1990, to firms and individuals who had previously asked FDA about the potential marketing of blood collection kits labeled for HIV-1 antibody testing. FDA held an open public meeting on April 6, 1989 to obtain comments on the potential marketing of these blood collection kits. FDA will be preparing a full report on the review of the comments received in response to the public meeting. In the interim, to ensure that all interested persons have access to the information in the April 18, 1990 letter, the text of the letter is being made available to the public through this notice.

FOR FURTHER INFORMATION CONTACT: Mary Gustafson, Center for Biologics Evaluation and Research (HFB-240), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, 310-443-5433.

SUPPLEMENTARY INFORMATION: In the Federal Register of February 17, 1989 (54 FR 7279), FDA announced its preliminary criteria for the acceptability of blood collection kits labeled for HIV-1 antibody testing and invited public comment on these criteria. In the notice, FDA also announced an open public meeting to discuss blood collection kits and home test kits that are designed to detect HIV-1 antibody and suggested several topics for discussion at the meeting. On April 6, 1989, FDA held an open public meeting to obtain comments on the criteria being applied to applications for premarket approval of blood collection kits labeled for HIV-1 antibody testing. Comments were also solicited on home test kits designed to detect evidence of infection with HIV-1.

FDA is preparing a report based on the comments received at the meeting as well as the comments received in writing in response to the notice. As an interim step in this ongoing review process, FDA's Center for Biologics Evaluation and Review issued a letter on April 18, 1990, to those firms and

individuals who had previously asked FDA about marketing such products.

To ensure that all interested persons have access to the information contained in the April 18, 1990 letter, we are publishing it in the Federal Register. The text of the letter follows:
April 18, 1990.

Dear _____

We are writing to you in order to provide further information concerning blood collection kits labeled for HIV-1 testing. You had earlier expressed an interest in obtaining FDA approval to market such a device. As you know, FDA previously had determined that this device is classified by statute into class III, requiring premarket approval. In March 1988, prospective manufacturers and other interested parties were informed that only those premarket approval applications (PMA's) meeting certain listed criteria would be acceptable for filing. These criteria, as subsequently published in the Federal Register (54 FR 7280; February 17, 1989), were as follows:

1. Kits are labeled and marketed for professional use only within a health care environment (e.g., hospitals, medical clinics, doctor's offices, sexually transmitted disease clinics, HIV-1 counseling and testing centers, and mental health clinics);
2. Kits provide for the collection of a venipuncture or other appropriately validated sample by one who is recognized by a state or local authority to perform such procedures;
3. The testing sequence for all samples collected with the kits includes use of a licensed screening test for HIV-1 antibody and, for those samples testing positive by the screening test, the use of an additional more specific test (i.e., Western blot or comparable test). It is recommended that a licensed test which is more specific for HIV-1 antibody be utilized. However, the agency may accept a properly validated unlicensed test until licensed tests are more widely available;
4. The instructions for sample collections, storage, shipping, and testing conform with, or are validated as the equivalent to, the package insert instructions for the specific licensed HIV-1 antibody test kit used to test samples; and
5. All results of testing are reported directly to a professional health care provider for reporting and interpretation of the result to the person requesting the test, as well as for counseling of the individual.

As you may know, on April 6, 1989, FDA held a public meeting to provide a forum for discussion of FDA's policy on blood collection kits labeled for HIV-1 antibody testing and related issues. The agency also provided an opportunity for interested persons to submit written comments on these issues by May 5, 1989. Based on all the available information, including information from the oral and written comments related to the April 1989 meeting as well as information on advances in the treatment of HIV infection, FDA has been reconsidering its position on the filing of PMA's for such blood collection kits.

FDA has not at this time changed its position concerning the validity of any of the

five criteria listed in the February 17, 1989 Federal Register notice. Should a manufacturer wish to pursue marketing a blood collection kit for anti-HIV-1 testing intended for home use, the FDA is, however, willing to review with the manufacturer the suitable information to be included in a PMA so that the agency can make a determination that the application is sufficiently complete to permit its filing and substantive review. This process does not mean, of course, that such PMA's would necessarily be approvable. Approval would be dependent upon a finding that information and data submitted demonstrate the safety and effectiveness of such blood collection kits for home use. It does mean that FDA believes that manufacturers could proceed to conduct studies under investigational device exemptions (IDE's) and submit PMA's on home blood collection kits labeled for HIV-1 antibody testing that FDA would find acceptable for review.

If you are interested in pursuing such IDE studies and possible filing of a PMA for a home blood collection kit labeled for HIV-1 antibody testing, you may wish to contact Ms. Leslie Abelson, Division of Product Certification at 301-443-5433.

Sincerely yours,

Paul D. Parkman,

Director, Center for Biologics, Evaluation and Research.

Dated: July 20, 1990.

Ronald G. Chesemora,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 90-1765 Filed 7-27-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90F-0225]

Albright and Wilson Americas; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Albright and Wilson Americas has filed a petition proposing that the food additive regulations be amended to provide for the safe use of dimethylamine-epichlorohydrin copolymer as a sizing agent in the manufacture of paper and paperboard intended for use in contact with food.

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

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP OB4215), has been filed by Albright and Wilson Americas, c/o Delta Analytical

Corp., 1414 Fenwick Lane, Silver Spring, MD 20910, proposing § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of dimethylamine-epichlorohydrin copolymer as a sizing agent in the manufacture of paper and paperboard intended for use in contact with 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: July 20, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-17660 Filed 7-27-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90F-0220]

Hoechst Celanese Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: NOTICE.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Hoechst Celanese Corp. has filed a petition proposing that the food additive regulations be amended to permit the use of acesulfame potassium as a nonnutritive sweetener in all nonalcoholic beverages, including beverage bases.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, 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: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 0A4212) has been filed by Hoechst Celanese Corp., Route 202-206 North, Somerville, NJ 08876, proposing that § 172.900 *Acesulfame potassium* (21 CFR 172.800) be amended to permit the use of acesulfame potassium as a nonnutritive sweetener in all nonalcoholic beverages, including beverage bases.

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: July 11, 1990.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 90-17661 Filed 7-27-90; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 90F-0217]

West Agro, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that West Agro, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of decanoic acid, nonanoic acid, phosphoric acid, propionic acid, and sodium 1-octanesulfonate, and sulfuric acid as an optional ingredient, as components of a sanitizing solution to be used in contact with food.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP OB4203) has been filed by West Agro, Inc., 11100 North Congress Ave., Kansas City, MO 64153-1222, proposing that § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) be amended to provide for the safe use of decanoic acid, nonanoic acid, phosphoric acid, propionic acid, and sodium 1-octanesulfonate, and sulfuric acid as an optional ingredient, as components of a sanitizing solution to be used in contact with 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: July 20, 1990.

Fred R. Shank,
Director, Center for Food Safety and Applied
Nutrition.

[FR Doc. 90-17662 Filed 7-27-90; 8:45 am]

BILLING CODE 4160-01-M

Public Health Service

National Institutes of Health; Statement of Organization, Functions, and Delegations of Authority

Part H, chapter HN (National Institutes of Health) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (40 FR 22859, May 27, 1975, as amended most recently at 55 FR 19998, May 14, 1990) is amended to reflect the changes indicated below in the titles of the programs of the National Institute of Child Health and Human Development (NICHD) (HNT). These changes will more properly reflect the organizations' reporting relationship to the Director, NICHD.

Section HN-B, Organization and Functions is amended by retitling the following programs as indicated:

(1) Under the heading *National Institute of Child Health and Human Development (HNT)*:

| Current title | Revised title |
|--|---|
| (A) Intramural Research Program (HNT-4). | Division of Intramural Research (HNT4). |
| (B) Scientific Review Program (HNT-6). | Division of Scientific Review (HNT6). |
| (C) Prevention Research Program (HNT-7). | Division of Prevention Research (HNT7). |

Dated: July 18, 1990.

William F. Raub,

Acting Director, NIH.

[FR Doc. 90-17589 Filed 7-27-90; 8:45 am]

BILLING CODE 4140-01-M

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

Part H, chapter HF (Food and Drug Administration) of the Statement of Organization, 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 parts 45 FR 33729, May 20, 1980, and 50 FR 51606, December 18, 1985) is amended to reflect organizational and functional changes in the Food and Drug Administration.

Within the Office of Management and Operations, Office of the Commissioner,

FDA proposes that the Office of Information Resources Management (OIRM) be established to incorporate all computer and information resource functions within one organizational component, and reduce the span of control. This new Office will consist of the Parklawn Computer Center and the Division of Information Resources Management which is being retitled as the Division of Information Management.

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

1. Delete subparagraph (h-5) Parklawn Computer Center (HFA-79) in its entirety and insert a new subparagraph (h-5) Office of Information Resources Management (HFA-79) reading as follows:

(h-5) *Office of Information Resources Management (HFA-79)*. Performs Agency information resources management functions.

Advises the Commissioner on information resources management issues.

Represents the Agency to the Office of the Assistant Secretary for Health and the Office of the Secretary on information resources management.

Manages the Parklawn Computer Center.

Serves the DHHS Executive Agent for Departmentwide connectivity.

2. Delete subparagraph (h-8) Division of Information Resources Management (HFA-73) in its entirety.

Dated: July 16, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-17675 Filed 7-27-90; 8:45 am]

BILLING CODE 4160-17-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[NV-930-00-4212-16; Nev-061603, N-22848, N-24788, N-40267, N-40271, N-40272, N-40279, N-40280]

Termination of Desert Land Classifications; Nevada

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: This action terminates desert land classifications Nev-061603, N-22848, N-24788, N-40267, N-40271, N-40272, N-40279, and N-40280.

EFFECTIVE DATE: Termination of the classifications is effective with the publication of this document.

FOR FURTHER INFORMATION CONTACT:

Vienna Wolder, BLM Nevada State Office, 850 Harvard Way, P.O. Box 12000, Reno, NV 89520, 702-785-6526.

SUPPLEMENTARY INFORMATION: Pursuant to section 7 of the Taylor Grazing Act (48 Stat. 1272), desert land classifications Nev-061603, N-22848, N-24788, N-40267, N-40271, N-40272, N-40279, and N-40280 are hereby terminated in their entireties. The following described lands are affected by this action:

Mount Diablo Meridian, Nevada

T. 10 N., R. 43 E.,

Sec. 28, E $\frac{1}{2}$ E $\frac{1}{2}$;

Sec. 33, NW $\frac{1}{4}$ NW $\frac{1}{4}$, E $\frac{1}{2}$ NW $\frac{1}{4}$,
NW $\frac{1}{4}$ SW $\frac{1}{4}$.

T. 3 N., R. 48 E.,

Sec. 3, Lots 1, 2, 5, S $\frac{1}{2}$ NE $\frac{1}{4}$, NW $\frac{1}{4}$ SE $\frac{1}{4}$.

T. 4 N., R. 48 E.,

Sec. 34, Lots 3, 4.

T. 7 N., R. 50 E.,

Sec. 26, S $\frac{1}{2}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ SE $\frac{1}{4}$;

Sec. 27, SE $\frac{1}{4}$ SE $\frac{1}{4}$;

Sec. 34, NE $\frac{1}{4}$ NE $\frac{1}{4}$;

Sec. 35, N $\frac{1}{2}$ NW $\frac{1}{4}$, NW $\frac{1}{4}$ NE $\frac{1}{4}$.

T. 4 N., R. 54 E.,

Sec. 7, Lot 3, NE $\frac{1}{4}$ SW $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$;

Sec. 14, All.

T. 4 N., R. 55 E.,

Sec. 7, Lots 1, 4, 5, 8, NE $\frac{1}{4}$, E $\frac{1}{2}$ SW $\frac{1}{4}$,
E $\frac{1}{2}$ NW $\frac{1}{4}$, SE $\frac{1}{4}$.

The area described aggregates 2,081.02 acres in Nye County.

The classifications were accomplished pursuant to the Desert Land Act (43 U.S.C. 231, as amended) and the Carey Act (43 U.S.C. 641-647, as amended) in response to eight desert land applications. All the applications except N-40267 were approved and entries allowed. Entry to the lands provided segregation from all other forms of appropriation under the public land laws, including location under the mining laws. None of the entries provided up for patent and the entries have been cancelled. Application N-40267 was rejected. The classifications are no longer considered appropriate and are hereby terminated.

The cancellations and rejection were noted to the official records on June 21, 1990, and on that date the lands became open to the operation of the public land laws and location under the mining laws.

Robert G. Steeler,

Deputy State Director, Operations.

[FR Doc. 90-17599 Filed 7-27-90; 8:45 am]

BILLING CODE 4310-HC-M