Biolectron, Inc., Hackensack, NJ, for premarket approval, under the Medical Device Amendments of 1976, of the OrthoPak Bone Growth Stimulator System. After reviewing the recommendation of the Orthopedic and Rehabilitation Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by May 9, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nirmal K. Mishra, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7156.

SUPPLEMENTARY INFORMATION: On July 18, 1985, Biolectron, Inc., Hackensack, NJ 07601, submitted to CDRH an application for premarket approval of the OrthoPak Bone Growth Stimulator System. The device is an electrical bone growth stimulating device intended for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for a minimum of 3 months (no change in the fracture callus).

On November 25, 1985, the Orthopedic and Rehabilitation Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On February 18, 1986, CDRH approved the application by a letter to the applicant from the Director of the Office of Device and Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Nirmal K. Mishra, (HFZ–410), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 306e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before May 9, 1986, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554–555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 1, 1986.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 86–7826 Filed 4–8–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86M-0137]

Hybritech, Inc.; Premarket Approval of Tandem®-R PSA Immunoradiometric Assay for the Quantitative Measurement of Prostate-Specific Antigen (PSA) in Serum

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Hybritech, Inc., San Diego, CA, for premarket approval, under the Medical Device Amendments of 1976, of the TANDEM®-R PSA Immunoradiometric Assay for the Quantitative Measurement of Prostate-Specific Antigen (PSA) in Serum. After reviewing the recommendation of the Immunology Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the application.

DATE: Petitions for administrative review by May 9, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: S.K. Vadlamudi, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION: On July 9, 1985, Hybritech, Inc., San Diego, CA 92121, submitted to CDRH an application for premarket approval of the TANDEM®-R PSA Immunoradiometric Assay for the Quantitative Measurement of Prostate-Specific Antigen (PSA) in Serum. The device is a Prostate-Specific Antigen (PSA) immunological test system intended for the quantitative serial measurement of PSA in human serum to aid in the prognosis and management of patients with prostate cancer.

On December 9, 1985, the Immunology Devices Panel, an FDA advisory committee, reviewed and recommended approval of the application. On February 25, 1986, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the

Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact S.K. Vadlamudi (HFZ–440)., address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g)), for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showinig that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register**. If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review all occur, and other details.

Petitioners may, at any time on or before May 9, 1986, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554–555, 571 (21 U.S.C. 360e(d), 360j(h)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: April 1, 1986.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 86–7827 Filed 4–8–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86G–0103]

Lonza, Inc.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Lonza, Inc., has filed a petition (GRASP 5G0304) proposing that hydrogenated starch hydrolysate is generally recognized as safe (GRAS) as a direct human food ingredient.

DATE: Comments by June 9, 1986.

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

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 5G0304) has been filed by Lonza, Inc., Fairlawn, NJ 07410, proposing that hydrogenated starch hydrolysate is GRAS as a direct human food ingredient.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the format requirements outlined in § 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

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), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Interested persons may on or before June 9, 1986, review the petition and/or file comments (two copies, identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch (address above). Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 1, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–7828 Filed 4–8–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86G–0104]

Victorian Chemical Co., Pty. Ltd.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a petition (GRASP 6G0312) has been filed on behalf of Victorian Chemical Co., Pty. Ltd., proposing to affirm that ethyl esters of fatty acids are generally recognized as safe (GRAS) for use in an aqueous emulsion for dehydrating grapes to raisins.

DATE: Comments by June 9, 1986.

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

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 6G0312) has been filed on behalf of Victorian Chemical Co., Pty. Ltd., P.O. Box 72, Richmond, Victoria 3121 Australia, proposing to affirm that ethyl esters of fatty acids are GRAS for use in an aqueous emulsion for dehydrating grapes to raisins.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the format requirements outlined in § 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

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), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Interested persons may, on or before June 9, 1986, review the petition and/or file comments (two copies, identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch (address above). Comments should include any available information that would be helpful in determining whether this substance is, or is not, GRAS. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 1, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-7829 Filed 4-8-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86G-0105]

Victorian Chemical Co. Pty., Ltd.; Filing of Petition for Affirmation of GRAS Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Victorian Chemical Co. Pty., Ltd., has filed a petition (GRASP 6G0311) proposing to affirm that sulfated butyl oleate is generally recognized as safe (GRAS) for use in an aqueous emulsion for dehydrating grapes to raisins.

DATE: Comments by June 9, 1986.

ADDRESS: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers, Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-9463.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP 6G0311) has been filed by the Victorian Chemical Co. Pty., Ltd., P.O. Box 71, Richmond, Victoria 3121, Australia. This petition proposes to affirm that sulfated butyl oleate is GRAS for use in an aqueous emulsion for dehydrating grapes to raisins.

The petition has been placed on display at the Dockets Management Branch (address above).

Any petition that meets the format requirements outlined in § 170.35 is filed by the agency. There is no prefiling review of the adequacy of data to support a GRAS conclusion. Thus, the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for GRAS affirmation.

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 signifciant impact and the evidence supporting that finding will be published in the **Federal Register** in accordance with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Interested persons may, on or before June 9, 1986, review the petition and/or file comments (two copies, identified with the docket number found in brackets in the heading of this document) with the Dockets Management Branch (address above). Comments should include any available information that would be helpful in determining whether the substance is, or is not, GRAS. A copy of the petition and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 1, 1986.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-7830 Filed 4-8-86; 8:45 am]

BILLING CODE 4160-01-M

Office of Human Development Services

Adjustments to Fiscal Year 1987 Federal Allotments to States for Developmental Disabilities Basic Support and Protection and Advocacy Formula Grant Programs

Correction

In FR Doc. 86-6968 appearing on page 10932 in the issue of Monday, March 31, 1986, make the following corrections in the table:

1. In the second column, for Colorado, the Basic Support entry should read "$468,404".

2. In the third column, for New Jersey, the Protection and Advocacy entry should read "$296,581".

3. In the third column, for American Samoa, the Basic Support entry should read "$160,000".

BILLING CODE 1505-01-M

Public Health Service

National Toxicology Program; Availability of Technical Report on Toxicology and Carcinogenesis Studies of Chrysotile Asbestos

The HHS National Toxicology Program today announces the availability of the Technical Report describing toxicology and carcinogenesis studies of chrysotile asbestos.

Lifetime toxicology and carcinogenesis studies of short-range (SR) and intermediate-range (IR) fiber length chrysotile asbestos were conducted in groups of 88-250 male and female F344/N rats. Both forms of asbestos were administered at a concentration of 1% in pelleted diet for the lifetime of the rats.

Under the conditions of these lifetime studies, short-range and intermediate-range chrysotile asbestos did not induce overt toxicity and did not affect survival when ingested at a level of 1% in the diet by male and female F344/N rats. There was no evidence of carcinogenicity [1] in male or female rats exposed to SR chrysotile asbestos or in female rats exposed to IR chrysotile asbestos. There was some evidence of carcinogencity in male rats exposed to IR chrysotile

[1] The NTP uses five categories of evidence of carcinogenicity to summarize the strength of the evidence observed in each animal study: two categories for positive results ("clear evidence" and "some evidence"), one category for undertain findings ("equivocal evidence"), one category for no observable effect ("no evidence"), and one category for studies that cannot be evaluated because of major flaws ("inadequate study").