FEDERAL TRADE COMMISSION

[Dkt. C–3729]

Pre-Paid Legal Services, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent order prohibits, among other things, an Oklahoma-based corporation from making certain false and misleading claims concerning the benefits and appropriateness of living trusts or any legal instrument or service it offers and requires the respondent to clearly and conspicuously disclose to consumers that such trusts may be legally challenged on similar grounds as wills, that living trusts may not be appropriate in all instances, and that the transfer of an individual's assets into a living trust is not included in the price of creating the trust. In addition, the respondent must offer a $165 refund to every purchaser of an American Association for Senior Citizens trust who hasn't already received a refund and who doesn't live in certain states that have already been offered partial refunds in connection with an earlier multi-state settlement.

DATES: Complaint and Order issued April 4, 1997.[1]

FOR FURTHER INFORMATION CONTACT: Janice Charter, Federal Trade Commission, Denver Regional Office, 1961 Stout St., Suite 1523, Denver, CO 80294, (303) 844–2272.

SUPPLEMENTARY INFORMATION: On Wednesday, January 29, 1997, there was published in the **Federal Register**, 62 FR 4290, a proposed consent agreement with analysis In the Matter of Pre-Paid Legal Services, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, N.W., Washington, D.C. 20580.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–17363 Filed 7–1–97; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[Dkt. C–3737]

SplitFire, Inc.; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent order prohibits, among other things, the Illinois spark plugs manufacturer from making fuel economy, emissions, horsepower, or cost savings claims without competent and reliable scientific evidence to support them. The consent order also prohibits misrepresentations regarding the existence, contents, validity, results, conclusions or interpretations of any test or study. In addition, the consent order requires the respondent to possess competent and reliable scientific evidence to substantiate claims in endorsement or testimonials.

DATES: Complaint and Order issued April 28, 1997.[1]

FOR FURTHER INFORMATION CONTACT: Laura Fremont, Federal Trade Commission, San Francisco Regional Office, 901 Market St., Suite 570, San Francisco, CA 94103. (415) 356–5270.

SUPPLEMENTARY INFORMATION: On Thursday, February 20, 1997, there was published in the **Federal Register**, 62 FR 7785, a proposed consent agreement with analysis In the Matter of Splitfire, Inc., for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, N.W., Washington, D.C. 20580.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–17364 Filed 7–1–97; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

[Dkt. C–3738]

Zale Corporation; Prohibited Trade Practices, and Affirmative Corrective Actions

AGENCY: Federal Trade Commission.

ACTION: Consent order.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair or deceptive acts or practices and unfair methods of competition, this consent order prohibits, among other things, the Texas-based chain of retail jewelry stores from misrepresenting the composition or origin of any imitation, cultured or natural pearl product. The consent order requires the respondent to include a word such as ''artificial,'' ''imitation,'' or simulated'' in close proximity to any representation that an imitation pearl product contains pearls; and to include a word such as ''cultured'' or ''cultivated'' in close proximity to any representation that a cultured pearl product contains pearls. In addition, the consent order requires the respondent, for three years, to make available to consumers in their stores an information sheet that describes the origin of imitation, cultured or natural pearls.

DATES: Complaint and Order issued April 28, 1997.[1]

FOR FURTHER INFORMATION CONTACT: Matthew Gold, Federal Trade Commission, San Francisco Regional Office, 901 Market St., Suite 570, San Francisco, CA. 94103. (415) 356–5276.

SUPPLEMENTARY INFORMATION: On Thursday, February 20, 1997, there was published in the **Federal Register,** 62 FR 7786, a proposed consent agreement with analysis In the Matter of Zale Corporation, for the purpose of soliciting public comment. Interested parties were given sixty (60) days in which to submit comments, suggestions or objections regarding the proposed form of the order.

No comments having been received, the Commission has ordered the issuance of the complaint in the form

[1] Copies of the Complaint and the Decision and Order are available from the Commission's Public Reference Branch, H–130, 6th Street & Pennsylvania Avenue, N.W., Washington, D.C. 20580.

contemplated by the agreement, made its jurisdictional findings and entered an order to cease and desist, as set forth in the proposed consent agreement, in disposition of this proceeding.

(Sec. 6, 38 Stat. 721; 15 U.S.C. 46. Interprets or applies sec. 5, 38 Stat. 719, as amended; 15 U.S.C. 45)

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–17365 Filed 7–1–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0251]

Biotronik, Inc.; Premarket Approval of Dromos DR/DR–A and Dromos SR/SR–B Cardiac Pacing Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of the application by Biotronik, Inc., Lake Oswego, OR, for premarket approval, under the Federal Food, Drug, and Cosmetic Act (the act), of the Dromos DR/DR–A and Dromos SR/SR–B Cardiac Pacing Systems. FDA's Center for Devices and Radiological Health (CDRH) notified the applicant, by letter of October 11, 1996, of the approval of the application.

DATES: Petitions for administrative review by August 1, 1997.

ADDRESSES: 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Robert J. Mazzaferro, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517.

SUPPLEMENTARY INFORMATION: On February 21, 1996, Biotronik, Inc., Lake Oswego, OR 97035–5369, submitted to CDRH an application for premarket approval of the Dromos DR/DR–A and Dromos SR/SR–B Cardiac Pacing Systems. The BIOTRONIK Dromos DR and Dromos SR are rate adaptive multiprogrammable pulse generators. The Dromos DR is an atrial-based dual-chamber pacemaker and the Dromos SR is a single-chamber pacemaker suitable for either atrial or ventricular pacing therapy. The Dromos DR and Dromos SR have an accelerometer-based sensor and a rate-adaptive algorithm designed to automatically adjust the pacing rate to meet the patient's level of exertion. Rate adaptive pacing with the Dromos DR and Dromos SR pulse generators is indicated for patients exhibiting chronotropic incompetence and who would benefit from increased pacing rates concurrent with physical activity. Generally accepted indications for long-term cardiac pacing include, but are not limited to: Sick sinus syndrome (i.e., bradycardia-tachycardia syndrome, sinus arrest, sinus bradycardia), sino-atrial (SA) block, second- and third-degree AV block, and carotid sinus syndrome. Patients who demonstrate hemodynamic benefit through maintenance of AV synchrony should be considered for one of the dual-chamber or atrial pacing modes. Dual-chamber modes are specifically indicated for treatment of conduction disorders that require both restoration of rate and AV synchrony such as AV nodal disease, diminished cardiac output or congestive heart failure associated with conduction disturbances, and tachyarrhythmias that are suppressed by chronic pacing.

In accordance with the provisions of section 515(c)(2) of the act (21 U.S.C. 360e(c)(2)) as amended by the Safe Medical Devices Act of 1990, this premarket approval application (PMA) was not referred to the Circulatory System Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, for review and recommendation because the information in the PMA substantially duplicates information previously reviewed by this panel.

On October 11, 1996, 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.

Opportunity for Administrative Review

Section 515(d)(3) of the act authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 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 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 the 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 August 1, 1997 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) (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: June 10, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–17288 Filed 7–1–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97M–0255]

DePuy, Inc.; Premarket Approval of DePuy 1 Bone Cement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its