PART 341—COLD, COUGH, ALLERGY, BRONCHODILATOR, AND ANTIASTHMATIC DRUG PRODUCTS FOR OVER–THE–COUNTER HUMAN USE

3. The authority citation for 21 CFR part 341 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

4. Section 341.20 is amended by revising paragraph (b)(1) to read as follows:

§ 341.20 Nasal decongestant active ingredients.

* * * * *

(b) * * *

(1) Levmetamfetamine.

* * * * *

5. Section 341.80 is amended by revising paragraphs (c)(2)(ii), (c)(2)(vii), and (d)(2)(i), and the heading of paragraph (d)(2)(viii) to read as follows:

§ 341.80 Labeling of nasal decongestant drug products.

* * * * *

(c) * * *

(2) * * *

(ii) *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for adults.* ''Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor.''

* * * * *

(vii) *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form and when labeled for children under 12 years of age.* ''Do not use this product for more than 7 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, ask a doctor.''

* * * * *

(d) * * *

(2) * * *

(i) *For products containing levmetamfetamine identified in § 341.20(b)(1) when used in an inhalant dosage form.* The product delivers in each 800 milliliters of air 0.04 to 0.150 milligrams of levmetamfetamine. Adults: 2 inhalations in each nostril not more often than every 2 hours. Children 6 to under 12 years of age (with adult supervision): 1 inhalation in each nostril not more often than every 2 hours. Children under 6 years of age: ask a doctor.

* * * * *

(viii) *Other required statements—For products containing levmetamfetamine or propylhexedrine identified in § 341.20(b)(1) or (b)(9) when used in an inhalant dosage form.* * * *

* * * * *

Dated: July 23, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20303 Filed 7–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 98N–0513]

Medical Devices; Neurological Devices; Classification of Cranial Orthosis

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the cranial orthosis into class II (special controls). The special controls that will apply to the cranial orthosis are restriction to prescription use, biocompatibility testing, and certain labeling requirements. The agency is taking this action in response to a petition submitted under the Federal, Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997. The agency is classifying cranial orthosis into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

EFFECTIVE DATE: August 31, 1998.

FOR FURTHER INFORMATION CONTACT: James E. Dillard, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the FDA regulations (21 CFR part 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification.

In accordance with section 513(f)(1) of the act, FDA issued an order on March 12, 1998, classifying the Dynamic Orthotic Cranioplasty (DOC™ Band) in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On March 31, 1998, Cranial Technologies, Inc., submitted a petition requesting classification of the DOC™ Band under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition and the medical literature, FDA determined that the DOC™ Band can be

classified in class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of safety and effectiveness of the device.

The device is assigned the generic name ''cranial orthosis,'' and it is identified as a device intended for use on infants from 3 to 18 months of age with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape.

FDA identified the following risks to health associated with this type of device: (1) Skin irritation, skin breakdown and subsequent infection due to excessive pressure on the skin; (2) head and neck trauma due to alteration of the functional center of mass of the head and the additional weight of the device especially with an infant who is still developing the ability to control his/her head and neck movements; (3) impairment of brain growth and development from mechanical restriction of cranial growth; (4) asphyxiation due to mechanical failure, poor fit, and/or excessive weight that alters the infant's ability to lift the head; (5) eye trauma due to mechanical failure, poor construction and/or inappropriate fit; and (6) contact dermatitis due to the materials used in the construction of the device.

FDA believes that the special controls described below address these risks and provide reasonable assurance of the safety and effectiveness of the device. Therefore, on May 29, 1998, FDA issued an order to the petitioner classifying the cranial orthosis as described previously into class II subject to the special controls described below. Additionally, FDA is codifying the classification of this device by adding new § 882.5970.

In addition to the general controls of the act, the cranial orthosis is subject to the following special controls in order to provide reasonable assurance of the safety and effectiveness of the device: (1) The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109; (2) the labeling of the device must include: (a) Contraindications for the use of the device on infants with synostosis or with hydrocephalus; (b) warnings indicating the need to: (i) Evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of head growth and to describe steps that should be taken in order to reduce the potential for restriction of cranial growth and possible impairment of brain growth and development and (ii) evaluate the skin at frequent intervals, e.g., every 3 to 4 hours, and to describe steps that should be taken if skin irritation or breakdown occurs; (c) precautions indicating the need to: (i) Additionally treat torticollis, if the positional plagiocephaly is associated with torticollis; (ii) evaluate device fit and to describe the steps that should be taken in order to reduce the potential for restriction of cranial growth, the possible impairment of brain growth and development and skin irritation and/or breakdown; and (iii) evaluate the structural integrity of the device and to describe the steps that should be taken to reduce the potential for the device to slip out of place and cause asphyxiation or trauma to the eyes or skin; (d) adverse events, i.e., skin irritation and breakdown that have occurred with the use of the device; (e) clinician's instructions for casting the infant, for fitting the device, and for care; and (f) parent's instructions for care and use of the device; (3) the materials must be tested for biocompatibility with testing appropriate for long term direct skin contact.

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so it is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of these devices from class III to class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Cranial Technologies, Inc., dated March 31, 1998.

2. Hellbusch, J. L., L. C. Hellbusch, and R. J. Bruneteau, ''Active Counter-Positioning Treatment of Deformational Plagiocephaly,'' *Nebraska Medical Journal*, vol. 80, pp. 344 to 349, 1995.

3. Moss, S. D. et. al., ''Diagnosis and Management of the Misshapen Head in the Neonate,'' *Pediatric Review*, vol. 4, pp. 4 to 8, 1993.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

List of Subjects in 21 CFR Part 882

Medical devices.

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 882.5970 is added to subpart F to read as follows:

§ 882.5970 Cranial orthosis.

(a) *Identification.* A cranial orthosis is a device that is intended for medical

purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from 3 to 18 months of age, with moderate to severe nonsynostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

(b) *Classification*. Class II (special controls) (prescription use in accordance with § 801.109 of this chapter, biocompatibility testing, and labeling (contraindications, warnings, precautions, adverse events, instructions for physicians and parents)).

Dated: July 21, 1998.

Elizabeth D. Jacobson,

Deputy Director for Science, Center for Devices and Radiological Health.

[FR Doc. 98–20308 Filed 7–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05–98–063]

RIN 2115–AE 46

Special Local Regulations for Marine Events; Prospect Bay, Maryland

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being adopted for the ''Thunder on the Narrows'' hydroplane races to be held on the waters of Prospect Bay near Kent Narrows, Maryland. These regulations are needed to protect boaters, spectators and participants from the dangers associated with the event. This action is intended to enhance the safety of life and property during the event.

DATES: This temporary final rule is effective from 12 p.m. EDT (Eastern Daylight Time) to 6 p.m. EDT on August 1 and August 2, 1998.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore Maryland, 21226–1791, telephone number (410) 576–2674.

SUPPLEMENTARY INFORMATION:

Regulatory History

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective less than 30 days after **Federal Register** publication. The application for this event was not received until June 24, 1998. Following normal rulemaking procedures would have been impractical since there is not sufficient time remaining to publish a proposed rule in advance of the event or to provide for a delayed effective date. Immediate action is needed to protect vessel traffic from the potential hazards associated with congested waterways.

Background and Purpose

The Kent Narrows Racing Association has submitted a marine event application to the U.S. Coast Guard for the ''Thunder on the Narrows'' hydroplane races, to be held on the waters of Prospect Bay on August 1 and 2, 1998. The event will consist of 75 hydroplanes racing in heats counter-clockwise around an oval race course. A large fleet of spectator vessels is anticipated. Due to the need for vessel control during the races, vessel traffic will be temporarily restricted to provide for the safety of spectators, participants and transiting vessels.

Discussion of Regulations

The Coast Guard will establish temporary special local regulations on specified waters of Prospect Bay. The temporary special local regulations will be in effect from 12 p.m. EDT (Eastern Daylight Time) to 6 p.m. EDT on August 1 and 2, 1998, and will restrict general navigation in the regulated area during the event. Except for persons or vessels authorized by the Coast Guard Patrol Commander, no person or vessel may enter or remain in the regulated area. These regulations are needed to control vessel traffic during the marine event to enhance the safety of participants, spectators, and transiting vessels.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This conclusion is based on the fact that the regulated areas will only be in effect for a limited amount of time, and extensive advisories have been and will be made to the affected Maritime Community so that they may adjust their schedules accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as ''small business concerns'' under section 3 of the Small Business Act (15 U.S.C. 632). Because it expects the impact of this rule to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this temporary final rule will not have a significant economic impact on a substantial number of small entities because of the event's short duration.

Collection of Information

These regulations contain no Collection of Information requirements under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Federalism

The Coast Guard has analyzed this rule under the principles and criteria contained in Executive Order 12612 and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this rule and concluded that, under figure 2–1, paragraph (34)(h) of COMDTINST M16475.1C, this rule is categorically excluded from further environmental documentation. Special local regulations issued in conjunction with a regatta or marine parade are excluded under that authority.

List of Subjects in 33 CFR Part 100

Marine Safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

Temporary Regulations

In consideration of the foregoing, Part 100 of Title 33, Code of Federal Regulations is amended as follows:

PART 100—[AMENDED]

1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233; 49 CFR 1.46 and 33 CFR 100.35.