demonstrate that its verification procedures meet the purposes and objectives of the U.S. requirement. It is worth noting that the purposes and objectives of each provision of the seafood HACCP regulations are addressed in the preambles to the regulations when issued as a proposal (59 FR 4142, January 28, 1994) and as a final rule (December 18, 1995).

FDA's seafood HACCP requirements do not replace or supersede the Good Manufacturing Practices regulations for all foods in part 110 (see section VII.B.2 of this document). These provisions provide basic good manufacturing practices for all foods. Countries seeking a determination of equivalence must always demonstrate SPS measures that meet the objectives and purposes of part 110, regardless of the types of food that are to be the subject of the equivalence determination.

In addition to the seven principles cited above, FDA's seafood HACCP regulations require processors to engage in a sanitation program as a prerequisite to HACCP (§ 123.11). The importance of good sanitation as a prerequisite to HACCP is internationally recognized, as exemplified by the discussions on this subject at the most recent meeting of the Codex Alimentarious Committee on Fish and Fishery Products. The FDA prerequisite program requires processors to monitor and keep records of how, on a daily basis, they are meeting the conditions and practices specified in part 110 relating to eight fundamental areas of sanitation. Countries seeking equivalence should have in place measures that meet the purposes and objectives of the U.S. prerequisite requirements for sanitation.

*B. FDA's Seafood HACCP Guidelines*

FDA's seafood HACCP regulations provide the basic ground rules and principles for establishing HACCP systems. For example, processors must conduct a hazard analysis to determine what hazards must be controlled through the seven principles of HACCP. The regulations themselves contain little detailed guidance, however, regarding what the result of that hazard analysis should be in a given situation.

It would not be sufficient for a seafood processor to implement a HACCP system that failed to properly identify all specific hazards that should be identified during the hazard analysis process or that failed to establish appropriate controls for those hazards. Therefore, to provide guidance on what FDA would consider adequate in implementing the regulations, FDA has issued guidelines entitled the ''Fish and Fishery Products Hazards and Controls Guide.''

A country seeking a determination of equivalence for seafood should be able to demonstrate that hazards identified by its system, and the controls applied to those hazards, are appropriate to the purposes and objectives of the seven principles of HACCP. When making the determination for seafood, FDA will use the ''Fish and Fishery Products Hazards and Controls Guide'' in evaluating the exporting country's measures relating to the identification of hazards and the implementation of controls for those hazards.

As with a domestic processor, the exporting country has the opportunity to demonstrate that hazards are being adequately addressed through controls other than those described in the guidelines. Moreover, during consultations with that country, FDA would be willing to consider arguments that it is mistaken in its judgment regarding hazards and controls (just as FDA is willing to listen to arguments of this nature from domestic processors). In any event, there must ultimately be agreement between the two countries on the outcome of hazard analysis as well as on appropriateness of the other elements of the program (e.g., the adequacy of controls for the identified hazards).

At the outset, FDA plans to conduct its reviews on a product-by-product basis, until such time as the agency has sufficient confidence that it is no longer necessary to demonstrate adequate hazard analysis and controls for each product to be exported from a particular country.

*C. Raw Molluscan Shellfish*

The safety of molluscan shellfish for human consumption raw or partially cooked involves special considerations that must be taken into account when determining equivalence. Because they are sedentary, filter-feeding animals, molluscan shellfish can accumulate pathogens and other types of contaminants that are harmful to humans. For example, the positive relationship between harvesting areas contaminated by sewage pollution and shellfish-borne enteric disease is well established. Consequently, the condition of the water from which they are harvested is critical to the safety of molluscan shellfish, especially those that are intended to be consumed raw or partially cooked.

The U.S. program to ensure the safety of raw molluscan shellfish centers around a classification system for opening and closing molluscan shellfish harvesting waters. This aspect of the program is run by the governments of U.S. States that possess shellfish harvesting waters. FDA audits and evaluates these State programs. The procedures and standards for classifying waters, and for conducting other aspects of the program, are in a document known as the Manual of Operations of the National Shellfish Sanitation Program. From FDA's perspective, the Manual of Operations has the status of a guideline. Each State in the program, however, has agreed to strictly adhere to it. Moreover, each State in the program has agreed to reject shellfish that have not been grown, harvested, or otherwise processed in accordance with the Manual of Operations.

Several countries have entered into MOU's with FDA for the export of raw molluscan shellfish to the United States. (See FDA, International Cooperative Agreements (November 1996); available from National Technical Information Service.) Under these MOU's, the exporting countries have agreed to comply with the Manual of Operations, as if each were a U.S. State. Some of these countries have expressed an interest in renegotiating these agreements as equivalence agreements rather than compliance agreements.

The Manual of Operations is comprehensive and highly detailed. Where differences exist between an exporting country's program and details in the Manual of Operations, judgments must be made about the significance of the differences. Equivalence determinations should focus on matters of significance. A country seeking a determination of equivalence with the United States for raw molluscan shellfish needs to demonstrate that its program meets the purposes and objectives of the Manual of Operations wherever a significant difference exists between its program and the provisions of the Manual.

Dated: May 27, 1997.

**William B. Schultz,**

*Deputy Commissioner for Policy.*

[FR Doc. 97–14600 Filed 6–3–97; 8:45 am]

**BILLING CODE 4160–01–F**

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97N–0190]**

### Cranial Electrotherapy Stimulators; Submission of Safety and Effectiveness Information

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing an order requiring manufacturers of cranial electrotherapy stimulators (CES) to submit to FDA a summary of, and citation to, all information known or otherwise available to them respecting the device, including adverse safety and effectiveness information concerning the device that has not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA is requesting this information in order to determine whether the classification of the device should be revised, or whether a regulation requiring the submission of a premarket approval application (PMA) for the device should be issued. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to revoke the requirement that manufacturers of CES devices submit a PMA or notice of completion of a product development protocol (PDP) for the device.

**DATES:** Summaries and citations must be submitted by August 14, 1998.

**ADDRESSES:** Submit summaries and citations to the Documents Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

**FOR FURTHER INFORMATION CONTACT:** Doreen M. Melling, Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 513 of the act (21 U.S.C. 360c) requires the classification of medical devices into one of three regulatory classes: Class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were on the market before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This notice refers to both the devices that were on the market before May 28, 1976, and the substantially equivalent devices that were marketed on or after that date, as ''preamendments devices.''

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) establishes the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. However, submission of a PMA, or a notice of completion of a PDP is not required until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device, whichever is later. Also, such a device is exempt from the investigational device exemption (IDE) regulations of 21 CFR part 812 until the date stipulated by FDA in the final rule requiring the submission of a PMA for that device. If a PMA or a notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations.

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards, postmarket surveillance, patient registries, guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k)), recommendations, and other appropriate actions the agency deems necessary to provide such assurance. Thus, the SMDA modified the definition of class II devices to permit reliance on special controls, rather than performance standards alone, to provide reasonable assurance of safety and effectiveness.

The SMDA also added new section 515(i) of the act. This section requires FDA to order manufacturers of preamendments class III devices for which no final regulation has been issued requiring the submission of PMA's to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information which has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, or distributors to maintain records and to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or that a malfunction of the device is likely to cause death or serious injury on recurrence. Section 515 (i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III; and, for devices remaining in class III, to establish a schedule for the issuance of a rule requiring the submission of PMA's for the device.

In the **Federal Register** of August 24, 1995 (60 FR 43967), FDA issued a final rule to require the submission of a PMA or a notice of completion of a PDP for the CES device. FDA had not issued an order under section 515(i) of the act for the CES device before issuing this final rule. FDA has since become aware of additional information relevant to the possible reclassification of the device from class III to class II or class I. As a result, in the **Federal Register** of January 28, 1997 (62 FR 4023), FDA proposed to revoke the rule requiring the submission of a PMA or notice of completion of a PDP. At that time, FDA said that it believed that it is more appropriate to invoke the procedures under section 515(i) of the act for the CES device. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule based on the proposal (62 FR 4023).

In this document, FDA is requiring manufacturers of CES devices to submit a summary of, and citation to, all safety and effectiveness information known or otherwise available to them respecting such devices, including adverse information concerning the devices which has not been submitted under section 519 of the act.

## II. Statutory Authority and Enforcement

In addition to the provisions of section 515(i) of the act described in section I of this document, this order is issued under section 519 of the act, as implemented by § 860.7(g)(2) (21 CFR 860.7(g)(2)). This regulation authorizes FDA to require reports or other information bearing on the classification of a device. Section 519 of the act also requires the reporting of any death or serious injury caused by a device or by its malfunction.

Failure to furnish the information required by this order results in the device being misbranded under section 502(t) of the act (21 U.S.C. 352(t)) and is a prohibited act under sections 301(a) and (q) of the act (21 U.S.C. 331(a) and (q)). The agency will use its enforcement powers to deter noncompliance. Violations of section 301 of the act may be subject to seizure or injunction under sections 304(a) and 302(a) of the act (21 U.S.C. 334(a) and 332(a) respectively). In addition, violations under section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)), and criminal prosecution under section 303(a) of the act.

**III. Order**

The agency is hereby issuing this order under sections 515(i) and 519 of the act and § 860.7(g)(1) of the regulations. Under the order, the required information shall be submitted by August 14, 1998, so that FDA may begin promptly the process established by section 515(i) of the act to either revise or sustain the current classification of these devices.

**IV. Required Contents of Submissions**

By the date listed in section III of this document, all manufacturers currently marketing CES devices shall provide a summary of, and citation to, any information known or otherwise available to them respecting the devices, including adverse safety and effectiveness data which has not been submitted under section 519 of the act. FDA suggests that it may be in the best interest of submitters to summarize the information submitted under section 519 of the act to facilitate FDA's decision making, even though such information is not required.

The information should be submitted in one of the two following formats depending on whether the applicant is aware of any information which would support the reclassification of the device into class I (general controls) or class II (special controls). Information which would support the reclassification of the device must consist of adequate, valid scientific evidence showing that general controls alone (class I), or general controls and special controls (class II) will provide a reasonable assurance of the safety and effectiveness of the device.

For manufacturers who do not believe that existing information would support the reclassification of their device into class I or class II, the information provided should be submitted in the following format:

1. *Indications for use*. A general description of the disease or condition to be diagnosed, treated, cured, mitigated, or prevented, including a description of the patient population for which the device is intended.

2. *Device description*. An explanation of how the device functions, significant physical and performance characteristics of the device, and basic scientific concepts that form the basis for the device.

3. *Other device labeling*. Other device labeling that includes contraindications, warnings and precautions and/or promotional materials.

4. *Risks*. A summary of all adverse safety and effectiveness information and identification of the risks presented by the device as well as any mechanisms or procedures which will control the risk.

5. *Alternative practices and procedures*. A description of alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

6. *Summary of preclinical and clinical data*. The summary of preclinical and clinical data should include the conclusions drawn from the studies which support the safety and effectiveness of the device as well as special controls, if any, which address the adverse effects of the device on health. The summary should include a brief description of the objective of the studies, the experimental design, how the data were collected and analyzed, and a brief description of the results of the studies, whether positive, negative, or inconclusive. The summary of the clinical study(ies) should also include a discussion of the subject inclusion and exclusion criteria, the study population, reasons for patient discontinuations, and results of statistical analyses.

7. *Bibliography*. A copy of the key references, a brief summary of the salient features of each key reference, and a brief discussion of why the reference is relevant to an evaluation of the safety and effectiveness evaluation of the device.

Manufacturers who believe that existing information would support the reclassification of their device into class I or class II may either submit information using the format described below or may submit a formal reclassification petition which should include the information described below in addition to the information required under 21 CFR 860.123.

1. *Identification*. A brief narrative identification of the device. Where appropriate, this identification should include a listing of the materials, and the component parts, and a description of the intended use of the device.

2. *Risks to health*. An identification of the risks to health should summarize all adverse safety and effectiveness information, which have not been submitted under section 519 of the act particularly the most significant. The mechanisms or procedures which will control the risk should be described. A list of the general hazards associated with the device and a bibliography with copies of the referenced material should be provided.

3. *Recommendation*. A statement whether the manufacturer believes the device should be reclassified into class I or class II.

4. *Summary of reasons for recommendation*. Each manufacturer should include a summary of the reasons for requesting reclassification of its device and an explanation why it believes the device meets the statutory criteria for reclassification into class I or class II. Each manufacturer should also identify the special controls that it believes would be sufficient to provide reasonable assurance of the safety and effectiveness of its device if it believes the device should be reclassified into class II.

5. *Summary of valid scientific evidence on which the recommendation is based*. Manufacturers are advised that, when considering a formal reclassification petition, FDA will rely only upon valid scientific evidence to determine that there is a reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone (class I) or by general controls and special controls (class II). Valid scientific evidence consists of evidence from well-controlled investigations, particularly controlled studies, studies and objective trials without matched controls, well documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. (See § 860.7(c)(2)).

According to § 860.7(d)(1), there is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that the probable benefits to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of a device shall adequately demonstrate the absence of unreasonable risk of illness or injury associated with the use of the device for its intended uses and conditions for use. Moreover, in accordance to § 860.7(e)(1), there is reasonable assurance that a device is

effective when it can be determined, based upon valid scientific evidence, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

Manufacturers submitting a formal reclassification petition may wish to request two petitions as examples of successful reclassification petitions.

Magnetic resonance imaging devices, Docket Nos. 87P–0214/CP1 through CP13, and Nd:YAG Laser for posterior capsulotomy devices, Docket No. 86P–0083, were both reclassified from class III to class II following the submission of reclassification petitions. Both petitions are available upon submission of a Freedom of Information request to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–30, Rockville, MD 20857.

### V. Submission of Required Information

The summary of and citation to, any information required by the act must be submitted by August 14, 1998, to the Document Mail Center (address above).

Dated: May 28, 1997.

**Joseph A. Levitt,**

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

[FR Doc. 97–14599 Filed 6–3–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 97D–0189]**

### Recovery of Investigational New Drugs From Clinical Investigators; Revised Compliance Policy Guide; Availability

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of revised compliance policy guide (CPG) 7132c.05 entitled, ''Recovery of Investigational New Drugs from Clinical Investigators.'' Revised CPG 7132c.05 deletes obsolete drug citations in the Code of Federal Regulations. These references were superseded under the investigational new drug rewrite (IND Rewrite). Revised CPG 7132c.05 clarifies the terminology used to classify the recovery of investigational new drugs from clinical investigators consistent with existing regulations. In addition, consistent with the current CPG, this policy continues to apply to new animal drugs being studied under investigational new animal drug applications.

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of revised CPG 7132c.05 ''Recovery of Investigational New Drugs from Clinical Investigators '' (CPG 7132c.05) to the Director, Division of Compliance Policy (HFC–230), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance. Submit written comments on revised CPG 7132c.05 to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** JoAnne C. Marrone, Office of Regulatory Affairs (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–1242.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDA extensively revised its regulations governing the submission and review of IND's on March 19, 1987. These new regulations, called the IND Rewrite, were part of FDA's ongoing efforts to improve and streamline the new drug approval process. There are several provisions in the regulations that refer to the return of unused supplies to the sponsor of the IND. This revised CPG is intended to clarify the terminology to be used when it is necessary to recover investigational drugs from clinical investigators, consistent with the regulations.

This guidance document represents the agency's current thinking on the recovery of investigational drugs from clinical investigators. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

### II. Request for Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. Two copies of any comment are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. A copy of revised CPG 7132c.05 and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### III. Electronic Access

An electronic version of the revised CPG (Chapter 4, Sec. 444.100) is also available via Internet using the World Wide Web (www) (connect to the ORA home page at http://www.fda.gov/ora/compliance_ref/cpg).

Dated: May 27, 1997.

**Ronald G. Chesemore,**

*Associate Commissioner for Regulatory Affairs.*

[FR Doc. 97–14471 Filed 6–3–97; 8:45 am]

**BILLING CODE 4160–01–F**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

**[HCFA–2540 and HCFA-R–48]**

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, has submitted to the Office of Management and Budget (OMB) the following proposal for the collection of information. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Skilled Nursing Facility (SNF) and Skilled Nursing Facility Health Care Complex Cost Report, and supporting regulations 42 CFR 413.13, 413.20, 413.24 and 413.157; *Form No.:* HCFA–2540; *Use:* The Skilled Nursing Facility and Skilled Nursing Facility Health Care Complex Cost Report is the cost report to be used by freestanding SNFs to submit annual information to achieve a settlement of