



APR - 8 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

17 11 2004

Mr. A.R. Hoenninger
Managing Director C3SG
11103 San Pedro, Suite 117
San Antonio, TX 78216

Re: Reclassification of Colonic Irrigation Devices
Dated March 15, 2001
Docket No. 01P-0145

Dear Mr. Hoenninger,

On April 29, 2002 the Food and Drug Administration sent you a letter (enclosed) regarding the above referenced petition for reclassification pursuant to section 513(f)(2)(A) of the Federal Food, Drug, and Cosmetic Act (Act) stating that FDA had determined that the petition is administratively incomplete and therefore cannot be filed. We went on to enumerate specific areas that you would need to address before we could file the petition.

We have not received any additional information from you addressing those deficiencies. Therefore, we are closing out this petition for administrative purposes. If you wish, you may resubmit your petition at any time with the additional information.

If you have any questions about this letter, please contact Marjorie Shulman at (301) 594-1190.

Sincerely,

Philip J. Phillips
Deputy Director,
Science and Regulatory Policy
Office of Device Evaluation
Center for Devices and
Radiological Health

01P-0145

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APR 29 2002

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. A.R. Hoenninger
Managing Director C3SG
11103 San Pedro, Suite 117
San Antonio, Texas 78216

Re: Reclassification of Colonic Irrigation Devices
Dated: March 15, 2001

Dear Mr. Hoenninger:

The Food and Drug Administration has reviewed the above referenced petition for reclassification pursuant to section 513(f)(2)(A) of the Federal Food, Drug and Cosmetic Act (Act) and has determined the petition is administratively incomplete and therefore cannot be filed.

This petition does not include an adequate description of the major risks to health of the device, or a summary of all safety and effectiveness data supporting the recommended classification (i.e., a textual and tabular summary of clinical results of the significant published clinical studies), or a justification for your proposed classification based on a comparative analysis of the known risks to health and the available scientific evidence in support of safety and effectiveness. In addition, the petition not only fails to identify general and special controls which would apply to colonic irrigation systems as a Class II device, but provides no evidence to support that these controls would ensure the safety and effectiveness of the device for the intended uses.

Please note that the regulations governing reclassification of medical devices are included in the Medical Device Classification Procedures, Part 860 of Title 21, Code of Federal Regulations (21 CFR 860). Reclassification is specifically addressed in Subpart C, sections 860.120 through 860.136.

A copy of Part 860 is enclosed with this letter. Note that the definitions in section 860.3, the discussion of confidentiality and filing in section 860.5, the discussion of determination of safety and effectiveness and of valid scientific evidence in section 860.7, and the discussion of content and form in section 860.123, all bear directly on petitions for reclassification and should be well understood by all petitioners.

Should you choose to resubmit a petition in the future, the following components should be included in the submission:

1. Any subsequent submission should clearly and accurately state the action which is requested. The subject devices are currently classified as Class II when intended for colon cleansing when medically indicated, such as before radiological or endoscopic examinations, and Class III when intended for other uses. The reclassification petition you submitted (Tab 2, Section 2) stated that you were petitioning the FDA to change the classification for the colonic irrigation systems (including speculums and rectal nozzles) “from Class II to class III.”
2. A complete and thorough description of the device-type should be provided in any future submission and include:
 - a. Background information.
 - i. a description of the purpose of colonic irrigation systems;
 - ii. a brief discussion of colonic anatomy and function; and
 - iii. a complete summary of all devices currently available which highlights similarities and differences.
 - b. Specific Indications for Use.
 - c. Complete description of the type of device to be reclassified, including:
 - i. the number of components which form the device system;
 - ii. a description of each components’ physical property including diagrams where possible;
 - iii. a functional description of each component;
 - iv. a description of the interconnection mechanism between components;
 - v. a discussion of overall device-type function;
 - vi. a discussion of how the devices are disinfected and what components are disposable; and
 - vii. a summary of mechanical testing which includes data demonstrating that the device:
 - terminates function when water temperature exceeds 104°F;
 - terminates function when intracolonic pressure exceeds 2 psi;
 - can be cleaned of all disinfectant; and
 - complies with electrical standards.
3. Please be advised that reclassification applies not only to specific devices but rather to a generic type of devices which share common characteristics. Reclassification to Class II would apply to the marketing of all colonic irrigation systems, not only those from the

five specific manufacturers that you have listed. This concept should be incorporated within any future submission.

4. The reclassification petition (Tabs 4-7) describes a multitude of medical conditions and indications for which the device may be used. No valid scientific evidence, however, is provided to support the clinical benefit or utility of colonic irrigation systems in the treatment of any of these diseases or disorders. Any future submission should clearly state which of the indications are intended for reclassification from Class III to Class II. In addition, the specific clinical aspects of “general well being” for which you are requesting down-classification should be defined. For each of these indications, you must submit valid clinical data to support these claims. This should include summaries from well-controlled clinical investigations performed (in the United States or abroad) to evaluate the safety and effectiveness of the device for that specific indicated use. If you are unaware of any such data, you should consider designing and conducting such studies under significant-risk IDE status. You may wish to consider contacting the National Center for Complementary and Alternative Medicine of the National Institute of Health (www.nccam.nih.gov) for assistance in performing such studies. The data supplied in your submission is incomplete and based on unsubstantiated opinions. The FDA does not consider this type of information to be valid scientific evidence per 21 CFR 860.7.
5. A reclassification petition must demonstrate that the risks previously identified for a Class III device, in light of new information, can be adequately addressed by either general or special controls. When the device was originally classified by the Gastroenterology-Urology Classification Panel (Federal Register, January 23, 1981), several risks to health were identified. These risks, which the Panel felt could not be controlled by general or specific controls, became the basis for classifying this device as class III. The risks noted were:
 - tissue burns from water overheating;
 - perforation of the colon;
 - colon irritation; and
 - electrical injury.

Any future submission should address, at a minimum, the above risks to health as well as the risk of infection. A summary and analysis of all safety data supporting the recommended classification should be provided, as well as a listing of Medical Device Reports (MDRs) and a summary of published adverse events. In addition, evidence should be provided to be able to conclude that the identified risks are mitigated by new information or controlled by general/special controls. Each control should be described in a detailed manner.

The submission of information that addresses the issues noted above should allow us to file your reclassification petition, allow adequate information for a substantive review, and allow us to refer it to the appropriate advisory panel for their review and recommendation. Any further

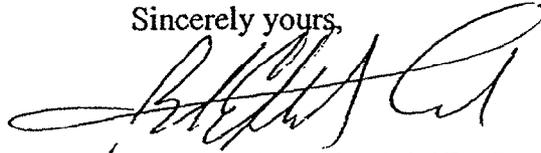
Page 4 – Mr. A. R. Hoenninger

correspondence pertaining to this petition should reference the above reclassification petition number and be submitted with a minimum of 5 copies.

If you have questions concerning the contents of this letter, please contact Ms. Kathleen Olvey at (301) 594-1220. We strongly suggest that you call to schedule either a meeting or teleconference to discuss your petition prior to re-submission.

If you need information or assistance concerning the reclassification regulations, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bernard E. Statland". The signature is fluid and cursive, with a large initial "B" and "S".

Bernard E. Statland, M.D., Ph.D.

Director

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosures

(b) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

§ 821.60 Retention of records

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

Sec.

860.1 Scope.

860.3 Definitions.

860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

860.7 Determination of safety and effectiveness.

Subpart B—Classification

860.84 Classification procedures for "old devices."

860.93 Classification of implants, life-supporting or life-sustaining devices.

860.95 Exemptions from sections 510, 519, and 520(f) of the act.

Subpart C—Reclassification

860.120 General.

860.123 Reclassification petition: Content and form.

860.125 Consultation with panels.

860.130 General procedures under section 513(e) of the act.

860.132 Procedures when the Commissioner initiates a performance standard or pre-

market approval proceeding under section 514(b) or 515(b) of the act.

860.134 Procedures for "new devices" under section 513(f) of the act and reclassification of certain devices.

860.136 Procedures for transitional products under section 520(l) of the act.

AUTHORITY: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

SOURCE: 43 FR 32993, July 28, 1978, unless otherwise noted.

Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to classification panels or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

§ 860.3 Definitions.

For the purposes of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Commissioner* means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

(c) *Class* means one of the three categories of regulatory control for medical devices, defined below:

(1) *Class I* means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.

(2) *Class II* means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance of its safety and effectiveness and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidance documents (including guidance on the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act), recommendations, and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(3) *Class III* means the class of devices for which premarket approval is or will be required in accordance with section 515 of the act. A device is in class III if insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of its safety and effectiveness or that

application of special controls described in paragraph (c)(2) of this section would provide such assurance and if, in addition, the device is life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, or if the device presents a potential unreasonable risk of illness or injury.

(d) *Implant* means a device that is placed into a surgically or naturally formed cavity of the human body. A device is regarded as an implant for the purpose of this part only if it is intended to remain implanted continuously for a period of 30 days or more, unless the Commissioner determines otherwise in order to protect human health.

(e) *Life-supporting or life-sustaining device* means a device that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

(f) *Classification questionnaire* means a specific series of questions prepared by the Commissioner for use as guidelines by classification panels preparing recommendations to the Commissioner regarding classification and by petitioners submitting petitions for reclassification. The questions relate to the safety and effectiveness characteristics of a device and the answers are designed to help the Commissioner determine the proper classification of the device.

(g) *Supplemental data sheet* means information compiled by a classification panel or submitted in a petition for reclassification, including:

- (1) A summary of the reasons for the recommendation (or petition);
- (2) A summary of the data upon which the recommendation (or petition) is based;
- (3) An identification of the risks to health (if any) presented by the device;
- (4) To the extent practicable in the case of a class II or class III device, a recommendation for the assignment of a priority for the application of the requirements of performance standards or premarket approval;
- (5) In the case of a class I device, a recommendation whether the device

should be exempted from any of the requirements of registration, record-keeping and reporting, or good manufacturing practice regulations;

(6) In the case of an implant or a life-supporting or life-sustaining device for which classification in class III is not recommended, a statement of the reasons for not recommending that the device be classified in class III;

(7) Identification of any needed restrictions on the use of the device, e.g., whether the device requires special labeling, should be banned, or should be used only upon authorization of a practitioner licensed by law to administer or use such device; and

(8) Any known existing standards applicable to the device, device components, or device materials.

(h) *Classification panel* means one of the several advisory committees established by the Commissioner under section 513 of the act and part 14 of this chapter for the purpose of making recommendations to the Commissioner on the classification and reclassification of devices and for other purposes prescribed by the act or by the Commissioner.

(i) *Generic type of device* means a grouping of devices that do not differ significantly in purpose, design, materials, energy source, function, or any other feature related to safety and effectiveness, and for which similar regulatory controls are sufficient to provide reasonable assurance of safety and effectiveness.

(j) *Petition* means a submission seeking reclassification of a device in accordance with § 860.123.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58403, Dec. 10, 1992; 65 FR 56480, Sept. 19, 2000]

§ 860.5 Confidentiality and use of data and information submitted in connection with classification and reclassification.

(a) This section governs the availability for public disclosure and the use by the Commissioner of data and information submitted to classification panels or to the Commissioner in connection with the classification or reclassification of devices under this part.

(b) In general, data and information submitted to classification panels in connection with the classification of devices under § 860.84 will be available immediately for public disclosure upon request. However, except as provided by the special rules in paragraph (c) of this section, this provision does not apply to data and information exempt from public disclosure in accordance with part 20 of this chapter: Such data and information will be available only in accordance with part 20.

(c)(1) Safety and effectiveness data submitted to classification panels or to the Commissioner in connection with the classification of a device under § 860.84, which have not been disclosed previously to the public, as described in § 20.81 of this chapter, shall be regarded as confidential if the device is classified in to class III. Because the classification of a device under § 860.84 may be ascertained only upon publication of a final regulation, all safety and effectiveness data that have not been disclosed previously are not available for public disclosure unless and until the device is classified into class I or II, in which case the procedure in paragraph (c)(2) of this section applies.

(2) Thirty days after publication of a final regulation under § 860.84 classifying a device into class I or class II, safety and effectiveness data submitted for that device that had been regarded as confidential under paragraph (c)(1) of this section will be available for public disclosure and placed on public display in the office of the Dockets Management Branch, Food and Drug Administration unless, within that 30-day period, the person who submitted the data demonstrates that the data still fall within the exemption for trade secrets and confidential commercial information described in § 20.61 of this chapter. Safety and effectiveness data submitted for a device that is classified into class III by regulation in accordance with § 860.84 will remain confidential and unavailable for public disclosure so long as such data have not been disclosed to the public as described in § 20.81 of this chapter.

(3) Because device classification affects generic types of devices, in making determinations under § 860.84 concerning the initial classification of a

device, the classification panels and the Commissioner may consider safety and effectiveness data developed for another device in the same generic type, regardless of whether such data are regarded currently as confidential under paragraph (c)(1) of this section.

(d)(1) The fact of its existence and the contents of a petition for reclassification filed in accordance with § 860.130 or § 860.132 are available for public disclosure at the time the petition is received by the Food and Drug Administration.

(2) The fact of the existence of a petition for reclassification filed in accordance with § 860.134 or § 860.136 is available for public disclosure at the time the petition is received by the Food and Drug Administration. The contents of such a petition are not available for public disclosure for the period of time following its receipt (not longer than 30 days) during which the petition is reviewed for any deficiencies preventing the Commissioner from making a decision on it. Once it is determined that the petition contains no deficiencies preventing the Commissioner from making a decision on it, the petition will be filed with the Dockets Management Branch and its entire contents will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. If, during this 30-day period of time, the petition is found to contain deficiencies that prevent the Commissioner from making a decision on it, the petitioner will be so notified and afforded an opportunity to correct the deficiencies.

Thirty days after notice to the petitioner of deficiencies in the petition, the contents of the petition will be available for public disclosure unless, within that 30 days, the petitioner submits supplemental material intended to correct the deficiencies in the petition. The Commissioner, in the Commissioner's discretion, may allow withdrawal of a deficient petition during the 30-day period provided for correcting deficiencies. Any supplemental material submitted by the petitioner, together with the material in the original petition, is considered as a new petition. The new petition is reviewed for

deficiencies in the same manner as the original petition, and the same procedures for notification and correction of deficiencies are followed. Once the petitioner has corrected the deficiencies, the entire contents of the petition will be available for public disclosure and subject to consideration by classification panels and by the Commissioner in making a decision on the petition. Deficient petitions which have not been corrected within 180 days after notification of deficiency will be returned to the petitioner and will not be considered further unless resubmitted.

(e) The Commissioner may not disclose, or use as the basis for reclassification of a device from class III to class II, any information reported to or otherwise obtained by the Commissioner under section 513, 514, 515, 516, 518, 519, 520(f), 520(g), or 704 of the act that falls within the exemption described in § 20.61 of this chapter for trade secrets and confidential commercial information. The exemption described in § 20.61 does not apply to data or information contained in a petition for reclassification submitted in accordance with § 860.130 or § 860.132, or in a petition submitted in accordance with § 860.134 or § 860.136 that has been determined to contain no deficiencies that prevent the Commissioner from making a decision on it. Accordingly, all data and information contained in such petitions may be disclosed by the Commissioner and used as the basis for reclassification of a device from class III to class II.

(f) For purposes of this section, safety and effectiveness data include data and results derived from all studies and tests of a device on animals and humans and from all studies and tests of the device itself intended to establish or determine its safety and effectiveness.

§ 860.7 Determination of safety and effectiveness.

(a) The classification panels, in reviewing evidence concerning the safety and effectiveness of a device and in preparing advice to the Commissioner, and the Commissioner, in making determinations concerning the safety and effectiveness of a device, will apply the rules in this section.

(b) In determining the safety and effectiveness of a device for purposes of classification, establishment of performance standards for class II devices, and premarket approval of class III devices, the Commissioner and the classification panels will consider the following, among other relevant factors:

(1) The persons for whose use the device is represented or intended;

(2) The conditions of use for the device, including conditions of use prescribed, recommended, or suggested in the labeling or advertising of the device, and other intended conditions of use;

(3) The probable benefit to health from the use of the device weighed against any probable injury or illness from such use; and

(4) The reliability of the device.

(c)(1) Although the manufacturer may submit any form of evidence to the Food and Drug Administration in an attempt to substantiate the safety and effectiveness of a device, the agency relies upon only valid scientific evidence to determine whether there is reasonable assurance that the device is safe and effective. After considering the nature of the device and the rules in this section, the Commissioner will determine whether the evidence submitted or otherwise available to the Commissioner is valid scientific evidence for the purpose of determining the safety or effectiveness of a particular device and whether the available evidence, when taken as a whole, is adequate to support a determination that there is reasonable assurance that the device is safe and effective for its conditions of use.

(2) Valid scientific evidence is evidence from well-controlled investigations, partially 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 exist-

ence 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. Such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable.

(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 of use.

(2) Among the types of evidence that may be required, when appropriate, to determine that there is reasonable assurance that a device is safe are investigations using laboratory animals, investigations involving human subjects, and nonclinical investigations including in vitro studies.

(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.

(2) The valid scientific evidence used to determine the effectiveness of a device shall consist principally of well-controlled investigations, as defined in paragraph (f) of this section, unless the Commissioner authorizes reliance upon other valid scientific evidence which the Commissioner has determined is sufficient evidence from which to determine the effectiveness of a device, even in the absence of well-controlled investigations. The Commissioner may make such a determination where the

requirement of well-controlled investigations in paragraph (f) of this section is not reasonably applicable to the device.

(f) The following principles have been developed over a period of years and are recognized by the scientific community as the essentials of a well-controlled clinical investigation. They provide the basis for the Commissioner's determination whether there is reasonable assurance that a device is effective based upon well-controlled investigations and are also useful in assessing the weight to be given to other valid scientific evidence permitted under this section.

(1) The plan or protocol for the study and the report of the results of a well-controlled investigation shall include the following:

(i) A clear statement of the objectives of the study;

(ii) A method of selection of the subjects that:

(a) Provides adequate assurance that the subjects are suitable for the purposes of the study, provides diagnostic criteria of the condition to be treated or diagnosed, provides confirmatory laboratory tests where appropriate and, in the case of a device to prevent a disease or condition, provides evidence of susceptibility and exposure to the condition against which prophylaxis is desired;

(b) Assigns the subjects to test groups, if used, in such a way as to minimize any possible bias;

(c) Assures comparability between test groups and any control groups of pertinent variables such as sex, severity or duration of the disease, and use of therapy other than the test device;

(iii) An explanation of the methods of observation and recording of results utilized, including the variables measured, quantitation, assessment of any subject's response, and steps taken to minimize any possible bias of subjects and observers;

(iv) A comparison of the results of treatment or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be specified and an explanation provided of the methods employed to minimize any possible bias of the observers and analysts of

the data. Level and methods of "blinding," if appropriate and used, are to be documented. Generally, four types of comparisons are recognized:

(a) *No treatments.* Where objective measurements of effectiveness are available and placebo effect is negligible, comparison of the objective results in comparable groups of treated and untreated patients;

(b) *Placebo control.* Where there may be a placebo effect with the use of a device, comparison of the results of use of the device with an ineffective device used under conditions designed to resemble the conditions of use under investigation as far as possible;

(c) *Active treatment control.* Where an effective regimen of therapy may be used for comparison, e.g., the condition being treated is such that the use of a placebo or the withholding of treatment would be inappropriate or contrary to the interest of the patient;

(d) *Historical control.* In certain circumstances, such as those involving diseases with high and predictable mortality or signs and symptoms of predictable duration or severity, or in the case of prophylaxis where morbidity is predictable, the results of use of the device may be compared quantitatively with prior experience historically derived from the adequately documented natural history of the disease or condition in comparable patients or populations who received no treatment or who followed an established effective regimen (therapeutic, diagnostic, prophylactic).

(v) A summary of the methods of analysis and an evaluation of the data derived from the study, including any appropriate statistical methods utilized.

(2) To insure the reliability of the results of an investigation, a well-controlled investigation shall involve the use of a test device that is standardized in its composition or design and performance.

(g)(1) It is the responsibility of each manufacturer and importer of a device to assure that adequate, valid scientific evidence exists, and to furnish such evidence to the Food and Drug Administration to provide reasonable assurance that the device is safe and

effective for its intended uses and conditions of use. The failure of a manufacturer or importer of a device to present to the Food and Drug Administration adequate, valid scientific evidence showing that there is reasonable assurance of the safety and effectiveness of the device, if regulated by general controls alone, or by general controls and performance standards, may support a determination that the device be classified into class III.

(2) The Commissioner may require that a manufacturer, importer, or distributor make reports or provide other information bearing on the classification of a device and indicating whether there is reasonable assurance of the safety and effectiveness of the device or whether it is adulterated or misbranded under the act.

(3) A requirement for a report or other information under this paragraph will comply with section 519 of the act. Accordingly, the requirement will state the reason or purpose for such request; will describe the required report or information as clearly as possible; will not be imposed on a manufacturer, importer, or distributor of a classified device that has been exempted from such a requirement in accordance with § 860.95; will prescribe the time for compliance with the requirement; and will prescribe the form and manner in which the report or information is to be provided.

(4) Required information that has been submitted previously to the Center for Devices and Radiological Health need not be resubmitted, but may be incorporated by reference.

[43 FR 32993, July 28, 1978, as amended at 53 FR 11253, Apr. 6, 1988]

Subpart B—Classification

§ 860.84 Classification procedures for "old devices."

(a) This subpart sets forth the procedures for the original classification of a device that either was in commercial distribution before May 28, 1976, or is substantially equivalent to a device that was in commercial distribution before that date. Such a device will be classified by regulation into either class I (general controls), class II (special controls) or class III (premarket

approval), depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the device (§ 860.3(c)). This subpart does not apply to a device that is classified into class III by statute under section 513(f) of the act because the Food and Drug Administration has determined that the device is not "substantially equivalent" to any device subject to this subpart or under section 520(l) (1) through (3) of the act because the device was regarded previously as a new drug. In classifying a device under this section, the Food and Drug Administration will follow the procedures described in paragraphs (b) through (g) of this section.

(b) The Commissioner refers the device to the appropriate classification panel organized and operated in accordance with section 513 (b) and (c) of the act and part 14 of this chapter.

(c) In order to make recommendations to the Commissioner on the class of regulatory control (class I, class II, or class III) appropriate for the device, the panel reviews the device for safety and effectiveness. In so doing, the panel:

(1) Considers the factors set forth in § 860.7 relating to the determination of safety and effectiveness;

(2) Determines the safety and effectiveness of the device on the basis of the types of scientific evidence set forth in § 860.7;

(3) Answers the questions in the classification questionnaire applicable to the device being classified;

(4) Completes a supplemental data sheet for the device;

(5) Provides, to the maximum extent practicable, an opportunity for interested persons to submit data and views on the classification of the device in accordance with part 14 of this chapter.

(d) Based upon its review of evidence of the safety and effectiveness of the device, and applying the definition of each class in § 860.3(c), the panel submits to the Commissioner a recommendation regarding the classification of the device. The recommendation will include:

(1) A summary of the reasons for the recommendation;

(2) A summary of the data upon which the recommendation is based,

accompanied by references to the sources containing such data;

(3) An identification of the risks to health (if any) presented by the device;

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the act: section 510 (registration, product listing, and premarket notification) section 519 (records and reports) and section 520(f) (good manufacturing practice regulations) in accordance with § 860.95;

(5) In the case of a recommendation for classification into class II or class III, to the extent practicable, a recommendation for the assignment to the device of a priority for the application of a performance standard or a premarket approval requirement;

(6) In the case of a recommendation for classification of an implant or a life-supporting or life-sustaining device into class I or class II, a statement of why premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device, accompanied by references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(e) A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel if appropriate, and published a proposed regulation classifying the device. Preliminary panel recommendations are filed in the Dockets Management Branch's office upon receipt and are available to the public upon request.

(f) The Commissioner publishes the panel's recommendation in the FEDERAL REGISTER, together with a proposed regulation classifying the device, and other devices of that generic type, and provides interested persons an opportunity to submit comments on the recommendation and proposed regulation.

(g) The Commissioner reviews the comments and issues a final regulation classifying the device and other devices of that generic type. The regulation will:

(1) If classifying the device into class I, prescribe which, if any, of the requirements of sections 510, 519, and 520(f) of the act will not apply to the device and state the reasons for making the requirements inapplicable, in accordance with § 860.95;

(2) If classifying the device into class II or class III, at the discretion of the Commissioner, establish priorities for the application to the device of a performance standard or a premarket approval requirement;

(3) If classifying an implant, or life-supporting or life-sustaining device, comply with § 860.93(b).

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992; 64 FR 404, Jan. 5, 1999]

§ 860.93 Classification of implants, life-supporting or life-sustaining devices.

(a) The classification panel will recommend classification into class III of any implant or life-supporting or life-sustaining device unless the panel determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the panel recommends classification or reclassification of such a device into a class other than class III, it shall set forth in its recommendation the reasons for so doing together with references to supporting documentation and data satisfying the requirements of § 860.7, and an identification of the risks to health, if any, presented by the device.

(b) The Commissioner will classify an implant or life-supporting or life-sustaining device into class III unless the Commissioner determines that such classification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. If the Commissioner proposes to classify or reclassify such a device into a class other than class III, the regulation or order effecting such classification or reclassification will be accompanied by a full statement of the reasons for so doing. A statement of the reasons for not classifying or retaining the device in class III may be in the form of concurrence with the reasons for the recommendation of the classification

panel, together with supporting documentation and data satisfying the requirements of § 860.7 and an identification of the risks to health, if any, presented by the device.

§ 860.95 Exemptions from sections 510, 519, and 520(f) of the act.

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from some or all of the requirements of one or more of the following sections of the act: Section 510 (registration, product listing and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice regulations).

(b) A regulation or an order classifying or reclassifying a device into class I will specify which requirements, if any, of sections 510, 519, and 520(f) of the act the device is to be exempted from, together with the reasons for such exemption.

(c) The Commissioner will grant exemptions under this section only if the Commissioner determines that the requirements from which the device is exempted are not necessary to provide reasonable assurance of the safety and effectiveness of the device.

Subpart C—Reclassification

§ 860.120 General.

(a) Sections 513(e) and (f), 514(b), 515(b), and 520(l) of the act provide for reclassification of a device and prescribe the procedures to be followed to effect reclassification. The purposes of subpart C are to:

(1) Set forth the requirements as to form and content of petitions for reclassification;

(2) Describe the circumstances in which each of the five statutory reclassification provisions applies; and

(3) Explain the procedure for reclassification prescribed in the five statutory reclassification provisions.

(b) The criteria for determining the proper class for a device are set forth in § 860.3(c). The reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within

that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type.

(c) Any interested person may submit a petition for reclassification under section 513(e), 514(b), or 515(b). A manufacturer or importer may submit a petition for reclassification under section 513(f) or 520(l). The Commissioner may initiate the reclassification of a device classified into class III under sections 513(f) and 520(l) of the act.

[43 FR 32993, July 23, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§ 860.123 Reclassification petition: Content and form.

(a) Unless otherwise provided in writing by the Commissioner, any petition for reclassification of a device, regardless of the section of the act under which it is filed, shall include the following:

(1) A specification of the type of device for which reclassification is requested;

(2) A statement of the action requested by the petitioner, e.g., "It is requested that ___ device(s) be reclassified from class III to a class II";

(3) A completed supplemental data sheet applicable to the device for which reclassification is requested;

(4) A completed classification questionnaire applicable to the device for which reclassification is requested;

(5) A statement of the basis for disagreement with the present classification status of the device;

(6) A full statement of the reasons, together with supporting data satisfying the requirements of § 860.7, why the device should not be classified into its present classification and how the proposed classification will provide reasonable assurance of the safety and effectiveness of the device;

(7) Representative data and information known by the petitioner that are unfavorable to the petitioner's position;

(8) If the petition is based upon new information under section 513(e), 514(b), or 515(b) of the act, a summary of the new information;

(9) Copies of source documents from which new information used to support the petition has been obtained (attached as appendices to the petition).

(10) A financial certification or disclosure statement or both as required by part 54 of this chapter.

(b) Each petition submitted pursuant to this section shall be:

(1) Addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff (HFZ-215), 1350 Piccard Dr., Rockville, MD 20857;

(2) Marked clearly with the section of the act under which the petition is being submitted, i.e., "513(e)," "513(f)," "514(b)," "515(b)," or "520(1) Petition";

(3) Bound in a volume or volumes, where necessary; and

(4) Submitted in an original and two copies.

[43 FR 32993, July 28, 1978, as amended at 49 FR 14505, Apr. 12, 1984; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990; 63 FR 5254, Feb. 2, 1998; 65 FR 17137, Mar. 31, 2000]

§ 860.125 Consultation with panels.

(a) When the Commissioner is required to refer a reclassification petition to a classification panel for its recommendation under § 860.134, or is required, or chooses, to consult with a panel concerning a reclassification petition, such as under § 860.130, § 860.132, or § 860.136, the Commissioner will distribute a copy of the petition, or its relevant portions, to each panel member and will consult with the panel in one of the following ways:

(1) Consultation by telephone with at least a majority of current voting panel members and, when possible, nonvoting panel members;

(2) Consultation by mail with at least a majority of current voting panel members and, when possible, nonvoting panel members; and

(3) Discussion at a panel meeting.

(b) The method of consultation chosen by the Commissioner will depend upon the importance and complexity of the subject matter involved and the time available for action. When time and circumstances permit, the Commissioner will consult with a panel through discussion at a panel meeting.

(c) When a petition is submitted under § 860.134 for a post-enactment,

not substantially equivalent device ("new device"), in consulting with the panel the Commissioner will obtain a recommendation that includes the information described in § 860.84(d). In consulting with a panel about a petition submitted under § 860.130, § 860.132, or § 860.136, the Commissioner may or may not obtain a formal recommendation.

§ 860.130 General procedures under section 513(e) of the act.

(a) Section 513(e) of the act applies to reclassification proceedings under the act based upon new information.

(b) A proceeding to reclassify a device under section 513(e) may be initiated:

(1) On the initiative of the Commissioner alone;

(2) On the initiative of the Commissioner in response to a request for change in classification based upon new information, under section 514(b) or 515(b) of the act (see § 860.132); or

(3) In response to the petition of an interested person, based upon new information, filed in accordance with § 860.123.

(c) By regulation promulgated under this section, the Commissioner may change the classification from class III into:

(1) Class II if the Commissioner determines that special controls in addition to general controls would provide reasonable assurance of the safety and effectiveness of the device and there is sufficient information to establish special controls to provide assurance; or

(2) Class I if the Commissioner determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(d) The rulemaking procedures in § 10.40 of this chapter apply to proceedings to reclassify a device under section 513(e), except that the Commissioner may secure a recommendation with respect to a proposed reclassification from the classification panel to which the device was last referred. The panel will consider a proposed reclassification submitted to it by the Commissioner in accordance with the consultation procedures of § 860.125. Any recommendation submitted to the

Commissioner by the panel will be published in the FEDERAL REGISTER when the Commissioner promulgates a regulation under this section.

(e) Within 180 days after the filing of a petition for reclassification under this section, the Commissioner, by order published in the FEDERAL REGISTER, will either deny the petition or give notice of his intent to initiate a change in the classification of the device.

(f) If a device is reclassified under this section, the regulation effecting the reclassification may revoke any special control or premarket approval requirement that previously applied to the device but that is no longer applicable because of the change in classification.

(g) A regulation under this section changing the classification of a device from class III to class II may provide that such classification will not take effect until the effective date of a special control for the device established under section 514 of the act.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§ 860.132 Procedures when the Commissioner initiates a performance standard or premarket approval proceeding under section 514(b) or 515(b) of the act.

(a) Sections 514(b) and 515(b) of the act require the Commissioner to provide, by notice in the FEDERAL REGISTER, an opportunity for interested parties to request a change in the classification of a device based upon new information relevant to its classification when the Commissioner initiates a proceeding either to develop a performance standard for the device if in class II, or to promulgate a regulation requiring premarket approval for the device if in class III. In either case, if the Commissioner agrees that the new information warrants a change in classification, the Commissioner will publish in the FEDERAL REGISTER notice of the Commissioner's intent to initiate a proceeding under section 513(e) of the act and § 860.130 to effect such a change.

(b) The procedures for effecting a change in classification under sections 514(b) and 515(b) of the act are as follows:

(1) Within 15 days after publication of the Commissioner's notice referred to in paragraph (a) of this section, an interested person files a petition for reclassification in accordance with § 860.123.

(2) The Commissioner consults with the appropriate classification panel with regard to the petition in accordance with § 860.125.

(3) Within 60 days after publication of the notice referred to in paragraph (a) of this section, the Commissioner, by order published in the FEDERAL REGISTER, either denies the petition or gives notice of his intent to initiate a change in classification in accordance with § 860.130.

§ 860.134 Procedures for "new devices" under section 513(f) of the act and reclassification of certain devices.

(a) Section 513(f)(2) of the act applies to proceedings for reclassification of a device currently in class III by operation of section 513(f)(1) of the act. This category includes any device that is to be first introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, unless:

(1) It is substantially equivalent to another device that was in commercial distribution before that date and had not been regulated before that date as a new drug; or

(2) It is substantially equivalent to another device that was not in commercial distribution before such date but which has been classified into class I or class II; or

(3) The Commissioner has classified the device into class I or class II in response to a petition for reclassification under this section.

The Commissioner determines whether a device is "substantially equivalent" for purposes of the application of this section. If a manufacturer or importer believes that a device is not "substantially equivalent" but that it should not be in class III under the criteria in § 860.3(c), the manufacturer or importer may petition for reclassification under this section. A manufacturer or importer who believes that a device is "substantially equivalent" and wishes to proceed to market the device shall

submit a premarket notification in accordance with part 807 of this chapter. After considering a premarket notification, the Commissioner will determine whether the device is "substantially equivalent" and will notify the manufacturer or importer of such determination in accordance with part 807 of this chapter.

(b) The procedures for effecting reclassification under section 513(f) of the act are as follows:

(1) The manufacturer or importer of the device petitions for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it and allows the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) After determining that the petition contains no deficiencies precluding a decision on it, the Commissioner may for good cause shown refer the petition to the appropriate classification panel for its review and recommendation whether to approve or deny the petition.

(4) Within 90 days after the date the petition is referred to the panel, following the review procedures set forth in § 860.84(c) for the original classification of an "old" device, the panel submits to the Commissioner its recommendation containing the information set forth in § 860.84(d). A panel recommendation is regarded as preliminary until the Commissioner has reviewed it, discussed it with the panel, if appropriate, and developed a proposed reclassification order. Preliminary panel recommendations are filed in the Dockets Management Branch upon receipt and are available to the public upon request.

(5) The panel recommendation is published in the FEDERAL REGISTER as soon as practicable and interested persons are provided an opportunity to comment on the recommendation.

(6) Within 90 days after the panel's recommendation is received (and no

more than 210 days after the date the petition was filed), the Commissioner denies or approves the petition by order in the form of a letter to the petitioner. If the Commissioner approves the petition, the order will classify the device into class I or class II in accordance with the criteria set forth in § 860.3(c) and subject to the applicable requirements of § 860.93, relating to the classification of implants, life-supporting or life-sustaining devices, and § 860.95, relating to exemptions from certain requirements of the act.

(7) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

[43 FR 32993, July 28, 1978, as amended at 57 FR 58404, Dec. 10, 1992]

§ 860.136 Procedures for transitional products under section 520(i) of the act.

(a) Section 520(i)(2) of the act applies to reclassification proceedings initiated by a manufacturer or importer for reclassification of a device currently in class III by operation of section 520(i)(1) of the act. This section applies only to devices that the Food and Drug Administration regarded as "new drugs" before May 28, 1976.

(b) The procedures for effecting reclassification under section 520(i) are as follows:

(1) The manufacturer or importer of the device files a petition for reclassification of the device in accordance with § 860.123.

(2) Within 30 days after the petition is filed, the Commissioner notifies the petitioner of any deficiencies in the petition that prevent the Commissioner from making a decision on it, allowing the petitioner to supplement a deficient petition. Within 30 days after any supplemental material is received, the Commissioner notifies the petitioner whether the petition, as supplemented, is adequate for review.

(3) The Commissioner provides the petitioner an opportunity for a regulatory hearing conducted in accordance with part 16 of this chapter.

(4) The Commissioner consults with the appropriate classification panel

with regard to the petition in accordance with § 860.125.

(5) Within 180 days after the petition is filed (where the Commissioner has determined it to be adequate for review), the Commissioner, by order in the form of a letter to the petitioner, either denies the petition or classifies the device into class I or class II in accordance with the criteria set forth in § 860.3(c).

(6) Within a reasonable time after issuance of an order under this section, the Commissioner announces the order by notice published in the FEDERAL REGISTER.

PART 861—PROCEDURES FOR PERFORMANCE STANDARDS DEVELOPMENT

Subpart A—General

Sec.

- 861.1 Purpose and scope.
- 861.5 Statement of policy.
- 861.7 Contents of standards.

Subpart B—Procedures for Performance Standards Development and Publication

- 861.20 Summary of standards development process.
- 861.24 Existing standard as a proposed standard.
- 861.30 Development of standards.
- 861.34 Amendment or revocation of a standard.
- 861.36 Effective dates.
- 861.38 Standards advisory committees.

AUTHORITY: 21 U.S.C. 351, 352, 360c, 360d, 360gg-360ss, 371, 374; 42 U.S.C. 262, 264.

SOURCE: 45 FR 7484, Feb. 1, 1980, unless otherwise noted.

Subpart A—General

§ 861.1 Purpose and scope.

(a) This part implements section 514 of the Federal Food, Drug, and Cosmetic Act (the act) with respect to the establishment, amendment, and revocation of performance standards applicable to devices intended for human use.

(b) The Food and Drug Administration may determine that a performance standard, as described under special controls for class II devices in § 860.7(b) of this chapter, is necessary to provide

reasonable assurance of the safety and effectiveness of the device. Performance standards may be established for:

- (1) A class II device;
- (2) A class III device which, upon the effective date of the standard, is reclassified into class II; and
- (3) A class III device, as a condition to premarket approval under section 515 of the act, to reduce or eliminate a risk or risks associated with such device.

(c) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

[45 FR 7484, Feb. 1, 1980, as amended at 45 FR 23686, Apr. 8, 1980; 57 FR 58404, Dec. 10, 1992]

§ 861.5 Statement of policy.

In carrying out its duties under this section, the Food and Drug Administration will, to the maximum extent practical:

(a) Use personnel, facilities, and other technical support available in other Federal agencies;

(b) Consult with other Federal agencies concerned with standard setting and other nationally or internationally recognized standard setting entities; and

(c) Invite participation through conferences, workshops, or other means, by representatives of scientific, professional, industry, or consumer organizations who can make a significant contribution.

§ 861.7 Contents of standards.

Any performance standard established under this part will include such provisions as the Food and Drug Administration determines are necessary to provide reasonable assurance of the safety and effectiveness of the device or devices for which it is established. Where necessary to provide such assurance, a standard will address (but need not be limited to):

(a) Performance characteristics of the device;

(b) The design, construction, components, ingredients, and properties of the device, and its compatibility with power systems and connections to such systems;