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Donald P. Byrne,

Assistant Chief Counsel for Regulations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 874

[Docket No. 97P–0210]

Ear, Nose, and Throat Devices; Reclassification of Endolymphatic Shunt Tube With Valve

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the endolymphatic shunt tube with valve from class III to class II. The device is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease. This reclassification is based upon new information regarding the device contained in a reclassification petition submitted by E. Benson Hood Laboratories, Inc. (Hood Laboratories). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of a draft guidance document that would serve as the special control if this proposal becomes final. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments by November 13, 2001. See section XII for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: James K. Kane, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2080.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' to support reclassification under section 513(e) of the act must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., nonpublic information in a pending PMA. (See section 520c of the act (21 U.S.C. 360j(c).)

II. Regulatory History of the Device

In the **Federal Register** of November 6, 1986 (51 FR40378), FDA issued a final rule classifying the endolymphatic shunt tube with valve into class III (21 CFR 874.3850). The preamble to the proposal to classify the device (47 FR 3280, January 22, 1982) included the

recommendation of the Ear, Nose, and Throat Devices Panel (the Panel) regarding the classification of the device, a summary of the reasons the device should be subject to premarket approval, and identification of certain risks to health presented by the device. The Panel also recommended under section 513(c)(2)(A) of the act that a high priority for the application of section 515 of the act be assigned to the endolymphatic shunt tube with valve.

In the **Federal Register** of January 6, 1989 (54 FR 550), FDA published a notice of intent to initiate proceedings to require premarket approval of 31 preamendments class III devices assigned a high priority by FDA for application of premarket approval requirements. Among other things, the notice described the factors FDA takes into account in establishing priorities for initiating proceedings under section 515(b) of the act for issuing final rules requiring that preamendments class III devices have approved PMAs or declared completed product development protocol (PDPs). Using those factors, FDA determined that the endolymphatic shunt tube with valve, identified in § 874.3850, had a high priority for initiating a proceeding to require premarket approval. Accordingly, FDA began a rulemaking to require that the endolymphatic shunt tube with valve have an approved PMA or a PDP that has been declared completed.

In the **Federal Register** of May 4, 1990 (55 FR 18830), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the endolymphatic shunt tube with valve. In accordance with section 515(b)(2)(A) of the act, the preamble to the proposal included the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements, and the benefits to the public from the use of the device. The proposal also provided an opportunity for interested persons to comment on the proposed rule and to request a change in the classification of the device based on new information relevant to its classification. The period for requesting a change in the classification of the device closed on May 21, 1990. The period for commenting on the proposed rule closed on July 3, 1990. FDA did not receive any comments on the proposed rule.

On July 27, 1990, FDA received a petition from Hood Laboratories requesting a change in the classification of the endolymphatic shunt tube with valve from class III to class II. In response to requests from FDA for additional information, the Hood Laboratories petition was amended on April 8, 1991, and May 8, 1992, and filed on May 29, 1992. The Panel met on June 11, 1992, and recommended that the generic endolymphatic shunt tube with valve be reclassified from class III to class II. FDA disagreed with the Panel's recommendation. FDA found that the petition contained insufficient valid scientific evidence to determine that the controls described in section 513(a)(1)(B) of the act, in addition to the general controls applicable to all devices, would provide reasonable assurance of the device's safety and effectiveness for its intended use. In particular, FDA found that Hood Laboratories did not adequately address the issues of normal endolymphatic shunt pressure, the mode of action of the endolymphatic shunt tube with valve, flow characteristics, nor the risks associated with the use of the device. Accordingly, in the **Federal Register** of December 9, 1996 (61 FR 64909), FDA published a notice denying Hood Laboratories' petition to reclassify the endolymphatic shunt tube with valve from class III to class II.

On May 27, 1997, Hood Laboratories submitted a second petition (Ref. 1) in accordance with section 513(e) of the act and § 860.130 (21 CFR 860.130(a)), based on new information. The petitioner again requested reclassification of the endolymphatic shunt tube with valve from class III to class II and provided new information that adequately addressed FDA's concerns. As discussed further below, the petitioner submitted additional information regarding the risks associated with the endolymphatic shunt tube with valve. The new information showed that risks such as incidences of infection and clogging have similar occurrences in the valved and nonvalved endolymphatic shunts. The nonvalved device was classified into class II in 1986.

In accordance with section 513(e) of the act, § 860.130, and based on new information submitted or otherwise available to the agency with respect to the device, FDA is proposing to reclassify this device from class III to class II when the device is intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's disease. Consistent with the act and the regulation, FDA did not refer the petition to the Panel for its recommendation on the requested change in classification.

III. Device Description

The endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease. The device directs excess endolymph (the fluid contained in the membranous labyrinth of the ear) from the distended (enlarged or swollen) end of the endolymphatic system into the mastoid cavity (area of the temporal bone behind the ear) where reabsorption of the fluid occurs. The function of the pressure-limiting inner ear valve is to maintain the physiologically normal endolymphatic pressure and to ensure a unidirectional flow of endolymph.

Hood Laboratories' endolymphatic shunt tube with valve is the only device of its type in commercial distribution in the United States. It consists of a silicone catheter connected to a silicone tube that is inside a molded silicone body. The inside silicone tube has a slit valve at one end that allows the endolymph to exit. The silicone tube is inserted into the end of the endolymphatic sac to allow the endolymph to flow through the valve and into the mastoid cavity via the tail-like portion of the molded silicone body.

IV. Proposed Reclassification

FDA is proposing to reclassify the endolymphatic shunt tube with valve intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's disease from class III to class II. FDA believes that class II with the guidance document entitled ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve'' as the special control would provide reasonable assurance of safety and effectiveness of the device.

V. Risks to Health

When the device was classified into class III (51 FR 40378), FDA identified the primary risk to health presented by the device as a build up of fluid pressure in the inner ear due to a clogged or inoperative valve. FDA also believed that any surgical procedure to correct a defective valve presented additional risks to health, including infection due to revision surgery.

During the open public meeting (June 11, 1992) (Ref. 2) and review of the first Hood Laboratories reclassification petition, the Panel noted the similarities between the valved and nonvalved

shunts. Both the valved shunt device (class III) and the nonvalved shunt device (class II) drain excess endolymph from the distended end of the endolymphatic system into the mastoid cavity where resorption occurs. They further noted that both devices are intended to relieve the symptoms of Meniere's disease. The nonvalved shunt (class II device) permits the unrestricted flow of excess endolymph, while the valved shunt (class III device) is intended to control the flow of endolymph so that a normal endolymphatic pressure is maintained. During its review and discussion of the first petition (June 11, 1992), the Panel also acknowledged the difficulty in diagnosing, treating, and assessing the treatment plans for Meniere's disease and could not agree that the valved shunt is effective, but believed the device ''does something worthwhile'' in treating the symptoms. An invited guest speaker (Ref. 13) was concerned with the long-term functioning and integrity of the capillary tubing material, Supramid™, that was used in Hood Laboratories' shunt.

FDA noted that the benefits resulting from implantation of the endolymphatic shunt tube with valve, i.e., relief of vertigo, fluctuating hearing loss, tinnitus, and aural fullness which typifies Meniere's disease, appeared to be very similar to those resulting from implantation of the nonvalved shunt (Ref. 2). At the end of the meeting, FDA believed that there were potential benefits of the device in improving hearing, relief of vertigo, reduction of fullness in the ear, and mitigation of tinnitus. However, FDA believed that the petitioner had not adequately addressed the concerns about any buildup of fluid pressure in the inner ear due to a clogged or inoperative valved device, or the risk of infection from revision surgery. FDA believed that sufficient information existed regarding the risks associated with the device, but that the information needed to be assembled in such a way as to enable the agency to determine the safety and effectiveness of the device for its intended use.

Since that time, the petitioner has assembled additional information regarding the risks associated with the endolymphatic shunt tube with valve. Huang and Lin (Ref. 3) and Arenberg (Ref. 4) report that risks such as incidence of infections and clogging have similar occurrences in the valved and nonvalved endolymphatic shunts. Both shunts have been used for more than 20 years without reportable events of major or frequent safety or effectiveness problems. A search of FDA's medical device reporting (MDR) database reveals no deaths, serious injuries, or malfunctions. Although the claim of maintaining normal endolymphatic pressure by the valved shunt has not been established during its use over the past 20 years, FDA now believes that the risks previously identified with the valved shunt are not substantially different from those associated with the nonvalved shunt, and that special controls would provide reasonable assurance of the safety and effectiveness of the device.

VI. Summary of Reasons for Reclassification

After considering the new information contained in the petitioner's second petition, reevaluation of the data contained in the first petition, and more than 20 years of safe use of the device, FDA believes that special controls would provide reasonable assurance of the safety and effectiveness of the endolymphatic shunt tube with valve for its intended use. Observational data (Refs. 4 through 12) suggest that the shunt tube with valve may preserve hearing and reduce or eliminate symptoms in some persons with Meniere's disease who require surgical intervention. FDA believes that the endolymphatic shunt tube with valve intended to be implanted in the inner ear to relieve the symptoms of vertigo and hearing loss due to endolymphatic hydrops of Meniere's disease should be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is now sufficient information to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification is Based

In addition to the potential risks identified above, there are potential benefits of the device in improving hearing: (1) Relief of vertigo, (2) reduction of the fullness in the ear, and (3) mitigation of tinnitus. Observational data, including case reports submitted by Hood Laboratories, suggest that the valved shunt may preserve hearing and reduce or eliminate symptoms in persons with Meniere's disease who require surgical intervention (Refs. 4 through 12).

Wright (Ref. 9) maintains that the valved implant is superior to other methods of endolymphatic sac surgery after 7 years of experience and followup. Stahle (Ref. 7) reports that his results suggest that the pressure-sensitive, unidirectional inner ear valve is safe for long-term human implantation. He also reports that severely incapacitated patients can be relieved of vertigo without a destructive labyrinthectomy and can have significant sustained sensory hearing improvements as well. Other data suggest improved hearing in patients with the valved shunt as compared to patients implanted with the nonvalved shunt (Refs. 8 through 9). The determination of the lack of injury to the inner ear is based upon indirect evidence such as audiological testing and the evaluation of vertigo.

Based on the available information, FDA believes that the special control discussed below is capable of providing reasonable assurance of the safety and effectiveness of the endolymphatic shunt tube with valve with regard to the identified risks to health of this device.

VIII. Special Control

In addition to general controls, FDA believes that the guidance document entitled ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve,'' is an adequate special control to address the potential risks to health described for this device. Technical areas noted in the guidance to address the potential risks to health for this device include:

A. Labeling

Based on the scientific data available, FDA believes labeling that restricts the use of the device to patients considered appropriate by the attending physician will lessen the need for revision surgery.

B. Valve Performance

One hundred percent sample testing, prior to implantation, would demonstrate valve performance equivalency to any currently marketed device.

C. Materials Specification

Adherence to a bio-material with chemical stability in a physiological environment will address the concern of long-term functioning and integrity of the device.

D. Biocompatibility Testing

Adherence to biocompatibility testing procedures presented in FDA, Center for Devices and Radiological Health, Office of Device Evaluation, Blue Book Memorandum G95–1, ''Use of International Standard ISO–10993–1, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing,'' (Ref. 14) can control the risk of adverse tissue reaction.

E. Sterility Testing

Adherence to the sterility testing procedures presented in the guidance document entitled ''510(k) Sterility Review Guidance,'' January 2, 1990 (K90–1) (Ref. 15) can help control the risk of infection by guarding against the implantation of an unsterile device.

IX. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed reclassification 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.

X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive order and so 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 this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this reclassification action, if finalized, will not have a significant economic impact on a substantial number of small entities. In addition, this reclassification action 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 of 1995 is not required.

XI. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995. The special control does not require the respondent to submit additional information.

XII. Submission of Comments and Proposed Dates

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this proposal by November 13, 2001. Two copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for review in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA proposes that any final regulation based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

XIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. E. Benson Hood Laboratories, Inc., Reclassification Petition, May 27, 1997.

2. Transcript of 36th Meeting of the Ear, Nose, and Throat Devices Panel, Washington DC, June 11, 1992.

3. Huang, T. S. and C. C. Lin, ''Endolymphatic Sac Surgery for Meniere's Disease: A Composite Study of 339 Cases,'' *Laryngoscope*, vol. 95, pp. 1082–1086, 1985.

4. Letter from I. Kaufman Arenberg, Ear Center, P.C. to Lew Martin, Hood Laboratories, April 1, 1991.

5. Letter from J. William Wright III, Ear Institute of Indiana to Lew Martin, Hood Laboratories, January 15, 1991.

6. Letter from Tsun-Sheng Huang, Chang Gung Memorial Hospital to Lew Martin, March 14, 1991.

7. Stahle, J. and I. K. Arenberg, ''Ten Year Follow-up on the First Five Inner Ear Valve Implants for Intractable Vertigo in Sweden,'' *American Journal of Otology*, vol. 8, pp. 287–293, 1987.

8. Huang, T. S., ''Valve Implants Compared to Other Surgical Methods,'' *American Journal of Otology*, vol. 8, pp. 301–306, 1987.

9. Wright, J. W. and G. W. Hicks, ''Valved Implants in Endolymphatic Sac Surgery,'' *American Journal of Otology*, vol. 8, pp. 307–312, 1987.

10. Arenberg, I. K. and T. J. Balkany, ''Revision Endolymphatic Sac and Duct Surgery for Recurrent Meniere's Disease and Hydrops: Failure Analysis and Technical Aspects,'' *Laryngoscope*, p. 92, November 1982.

11. Arenberg, I. K., ''The Fine Points of Valve Implant Surgery for Hydrops: An Update,'' *American Journal of Otology*, vol. 3, No. 4, April 1982.

12. Arenberg, I. K. and W. P. R. Gibson, ''Nondestructive Surgery for Vertigo,'' *Operative Challenges in Otolaryngology Head and Neck Surgery*, edited by H. C. Pillsbury and M. M. Goldsmith, Mosby Yearbook Publishing, 1990.

13. Presentation by Mattox, D. E., Johns Hopkins University, ''Histology and Ultrastructure of Explanted Shunts with Valves,'' at the 36th Meeting of the Ear, Nose, and Throat Devices Panel, Washington DC, June 11, 1992.

14. FDA, Center for Devices and Radiological Health, Office of Device Evaluation, Blue Book Memorandum G95–1, ''Use of International Standard ISO–10993–1, Biological Evaluation of Medical Devices Part-1: Evaluation and Testing.''

15. FDA, Center for Devices and Radiological Health, Office of Device Evaluation, Guidance Document ''510(k) Sterility Review Guidance,'' February 12, 1990 (K90–1).

List of Subjects in 21 CFR Part 874

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend part 874 as follows:

PART 874—EAR, NOSE, AND THROAT DEVICES

1. The authority citation for 21 CFR part 874 continues to read as follows:

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

2. Section 874.3850 is revised to read as follows:

§ 874.3850 Endolymphatic shunt tube with valve.

(a) *Identification*. An endolymphatic shunt tube with valve is a device that consists of a pressure-limiting valve associated with a tube intended to be implanted in the inner ear to relieve symptoms of vertigo and hearing loss due to endolymphatic hydrops (increase in endolymphatic fluid) of Meniere's disease.

(b) *Classification*. Class II (special controls). The special control for this device is the FDA guidance document entitled ''Class II Special Controls Guidance Document: Endolymphatic Shunt Tube With Valve.''

Dated: August 2, 2001.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 01–20571 Filed 8–14–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 913

[SPATS No. IL–100–FOR]

Illinois Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a proposed amendment to the Illinois regulatory program (Illinois program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Illinois proposes revisions to and additions of statutory provisions concerning lands eligible for remining, the Illinois Interagency Committee on Surface Mining Control and Reclamation, lands unsuitable petitions, and rulemaking procedures. Illinois intends to revise its program to be consistent with SMCRA and to clarify ambiguities.

This document gives the times and locations that the Illinois program and the proposed amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that we will follow for the public hearing, if one is requested.

DATES: Written comments must be received by 4 p.m., e.s.t., September 14, 2001. If requested, we will hold a public hearing on the amendment on September 10, 2001. We will accept requests to speak at the hearing until 4 p.m., e.s.t. on August 30, 2001.

ADDRESSES: You should mail or hand deliver written comments and requests to speak at the hearing to Andrew R. Gilmore, Director, Indianapolis Field Office, at the address listed below.

You may review copies of the Illinois program, the amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Indianapolis Field Office.

Andrew R. Gilmore, Director, Indianapolis Field Office, Office of Surface Mining, Minton-Capehart Federal Building, 575 North Pennsylvania Street, Room 301, Indianapolis, IN 46204, Telephone: (317) 226–6700.

Illinois Department of Natural Resources, Office of Mines and Minerals, Land Reclamation Division, 300 W. Jefferson Street, Suite 300, Springfield, IL 62701, Telephone (217) 782–4970.

FOR FURTHER INFORMATION CONTACT: Andrew R. Gilmore, Director, Indianapolis Field Office. Telephone: (317) 226–6700. Internet: IFOMAIL@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Illinois Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act * * *'' and ''rules and regulations consistent with regulations issued by the Secretary'' pursuant to the Act. 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Illinois program on June 1, 1982. You can find background information on the Illinois program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the June 1, 1982, **Federal Register** (47 FR 23883). You can find later actions concerning the Illinois program at 30 CFR 913.15, 913.16, and 913.17.

II. Description of the Proposed Amendment

By letter dated June 28, 2001 (Administrative Record No. IL–5068), Illinois sent us an amendment to its program under SMCRA and the Federal regulations at 30 CFR 732.17(b). The proposed amendment consists of changes made to the Illinois Surface Coal Mining Land Conservation and Reclamation Act at 225 ILCS 720. The statutory changes were enacted through Public Act 90–0490 and became effective on August 17, 1997. Illinois sent the amendment at its own initiative. Below is a summary of the changes proposed by Illinois.

A. 225 ILCS 720/1.03 Definitions

Public Act 90–0490 amended subsection (a) by adding the following definition of ''lands eligible for remining'':

(9–a) ''Lands eligible for remining'' means those lands that would otherwise be eligible for expenditures under the Abandoned Mined Lands and Water Reclamation Act.

B. 225 ILCS 720/1.04 Advisory Council on Reclamation

1. Public Act 90–0490 revised subsection (a) by adding the language ''or his or her designee'' at the end of the first sentence. The revised sentence reads as follows:

(a) There is created the Surface Mining Advisory Council to consist of 9 members, plus the Director or his or her designee.

2. Public Act 90–0490 revised the first sentence of subsection (c) by adding the language ''Office of Mines and Minerals within the''. The revised sentence reads as follows:

(c) The Council shall act solely as an advisory body to the Director and to the Land Reclamation Division of the Office of Mines and Minerals within the Department.

C. 225 ILCS 720/1.05 Interagency Committee

Public Act 90–0490 amended Section 1.05 by adding a provision that abolished the Interagency Committee on Surface Mining Control and Reclamation. The provision reads as follows:

The Interagency Committee on Surface Mining Control and Reclamation shall be abolished on June 30, 1997. Beginning July 1, 1997, all programmatic functions formerly performed by the Interagency Committee on Surface Mining Control and Reclamation shall be performed by the Office of Mines and Minerals within the Department of Natural Resources, except as otherwise provided by Section 9.04 of this Act.

D. 225 ILCS 720/2.08 Standards for Approval of Permits and Revisions

Public Act 90–0490 added new subsection (e) concerning lands eligible for remining. This new subsection reads as follows:

(e) After the effective date of this amendatory Act of 1997, the prohibition of subsection (d) shall not apply to a permit application due to any violation resulting from an unanticipated event or condition at a surface coal mining operation on lands eligible for remining under a permit held by the person making such application. As used in this subsection:

(1) ''unanticipated event or condition'' means an event or condition encountered in a remining operation that was not