compliance approved for AD 86–07–02 are considered approved as alternative methods of compliance for this AD.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Brussels Aircraft Certification Division.

(g) All persons affected by this directive may obtain copies of the documents referred to herein upon request to Fairey Hydraulics Limited, Claverham, Bristol, England; or Pilatus Britten-Norman Limited, Bembridge, Isle of Wight, United Kingdom PO35 5PR, as applicable; or may examine these documents at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

(h) This amendment revises AD 86–07–02, Amendment 39–5382.

Issued in Kansas City, Missouri, on February 25, 1997.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–5491 Filed 3–5–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 97N–0023]

RIN 0910–AA99

Chlorofluorocarbon Propellants in Self-Pressurized Containers; Determinations That Uses Are No Longer Essential; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is seeking public comment on the policy it is considering for adoption on making and implementing determinations that uses of chlorofluorocarbons (CFC's) currently designated essential will no longer be deemed essential under the Clean Air Act due to the availability of safe and effective medical product technology that does not use CFC's. Essential-use products are exempt from FDA's ban on the use of CFC propellants in FDA-regulated products and the Environmental Protection Agency's (EPA's) ban on the use of CFC's in pressurized dispensers. The agency is taking this action because it is responsible for determining which products containing CFC's or other ozone-depleting substances are an essential use under the Clean Air Act. FDA is soliciting comments on this policy to assist the agency in striking an appropriate balance that will best protect the public health, both by ensuring the availability of an adequate number of treatment alternatives and by curtailing the release of ozone-depleting substances.

DATES: Written comments by May 5, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Wayne H. Mitchell, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2041.

SUPPLEMENTARY INFORMATION:

I. Background

Under § 2.125 (21 CFR 2.125), any food, drug, device, or cosmetic in a self-pressurized container that contains a CFC propellant for a nonessential use is adulterated, or misbranded, or both, under the Federal Food, Drug, and Cosmetic Act. This prohibition is based on scientific research indicating that CFC's reduce the amount of ozone in the stratosphere and thereby increase the amount of ultraviolet radiation reaching the earth. An increase in ultraviolet radiation will increase the incidence of skin cancer, and produce other adverse effects of unknown magnitude on humans, animals, and plants. Section 2.125(d) exempts from the adulteration and misbranding provisions of § 2.125(c) certain products containing CFC propellants that FDA determines provide unique health benefits that would not be available without the use of a CFC.

These products are referred to in the regulation as essential uses of CFC's and are listed in § 2.125(e). Under § 2.125(f), any person may petition FDA to request additions to the list of uses considered essential. To demonstrate that the use of a CFC is essential, the petition must be supported by an adequate showing that: (1) There are no technically feasible alternatives to the use of a CFC in the product; (2) the product provides a substantial health, environmental, or other public benefit that would not be obtainable without the use of the CFC; and (3) the use does not involve a significant release of CFC's into the atmosphere or, if it does, the release is warranted by the consequence if the use were not permitted.

EPA regulations implementing the provisions of section 610 of the Clean Air Act (42 U.S.C. 7671i) contain a general ban on the use of CFC's in pressurized dispensers, such as metered-dose inhalers (MDI's) (40 CFR 82.64(c) and 82.66(d)). These EPA regulations exempt from the general ban ''medical devices'' that FDA considers essential and that are listed in § 2.125(e). Section 601(8) of the Clean Air Act (42 U.S.C. 7671(8)) defines ''medical device'' as any device (as defined in the Federal Food, Drug, and Cosmetic Act), diagnostic product, drug (as defined in the Federal Food, Drug, and Cosmetic Act), and drug delivery system, if such device, product, drug, or drug delivery system uses a class I or class II ozone-depleting substance for which no safe and effective alternative has been developed (and, where necessary, approved by the Commissioner of Food and Drugs (the Commissioner)); and if such device, product, drug, or drug delivery system has, after notice and opportunity for public comment, been approved and determined to be essential by the Commissioner in consultation with the Administrator of EPA (the Administrator). Class I substances include CFC's, halons, carbon tetrachloride, methyl chloroform, methyl bromide, and other chemicals not relevant to this document (see 40 CFR part 82, appendix A to subpart A). Class II substances include hydrochlorofluorocarbons (HCFC's) (see 40 CFR part 82, appendix B to subpart A).

Production of ozone-depleting substances is being phased out worldwide under the terms of the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol), Sept. 16, 1987, S. Treaty Doc. No. 10, 100th Cong., 1st sess., 26 I.L.M. 1541 (1987). In accordance with the provisions of the Montreal Protocol, under authority of Title VI of the Clean Air Act (section 601 *et seq.*), manufacture of CFC's in the United States was generally banned as of January 1, 1996. To receive permission to manufacture CFC's in the United States after the phaseout date, manufacturers must obtain an exemption from the phaseout requirements from the Parties to the Montreal Protocol. Procedures for securing an essential-use exemption under the Montreal Protocol are described in the most recent request by EPA for applications for exemptions (60 FR 54349, October 23, 1995). Firms that wish to use CFC's manufactured after the phaseout date in medical devices (as

defined in section 601(8) of the Clean Air Act) covered under section 610 of the Clean Air Act must receive exemptions for essential uses under the Montreal Protocol.

Faced with the statutorily mandated phaseout of the production of CFC's, drug manufacturers are developing or have developed alternatives to MDI's and other self-pressurized drug dosage forms that do not contain ozone-depleting substances. Examples of these alternative dosage forms are MDI's that use such non-ozone-depleting substances as propellants and dry-powder inhalers (DPI's). FDA has recently approved the first CFC-free MDI, 3M Pharmaceuticals Inc.'s albuterol sulfate product, Proventil® HFA; although a determination has not yet been made on whether this product is a technically feasible alternative to the use of CFC's, this approval gives the subject matter of this advance notice of proposed rulemaking (ANPRM) a particular timeliness. The current or future availability of ''technically feasible alternatives to the use of a [CFC]'' may mean that the existing listing of a use in § 2.125(e) would no longer reflect current conditions. It is with this situation in mind that FDA is publishing this ANPRM regarding agency determinations that certain uses of ozone-depleting substances are no longer essential.

FDA has determined that it would be most productive to set out the following tentative policy on the elimination of essential uses in an ANPRM. The agency believes that providing an opportunity for the fullest public participation at the earliest possible stage in the agency decisionmaking process in this matter is appropriate to assist FDA in striking an appropriate balance that will best protect the public health, both by ensuring the availability of an adequate number of treatment alternatives and by curtailing the release of ozone-depleting substances. In striking this balance, FDA intends to assess a number of factors and is interested in public comment on them. In establishing its policy on the elimination of essential uses, FDA will assess the potential beneficial effects of reducing CFC emissions from drug products broadly, based on the amount of CFC emissions that would be avoided, the stratospheric ozone depletion that would be averted, and the resulting decline in incidence of UV-B-related adverse human health effects, including human cancers and cataracts. FDA will also assess the beneficial public health effects of continued availability of CFC-containing drug products broadly, based on the availability, safety, and efficacy of alternatives, in full consideration of differences in patients' medical circumstances, physiological sensitivity, and acceptability of use, among others. FDA is specifically soliciting comments on how it should develop information to assist in striking this balance and how it should further balance the need for timely action. FDA also believes that there is adequate time to publish an ANPRM and respond to comments but will endeavor to complete this rulemaking process in a timely fashion. Because the first potential technically feasible alternatives are just now coming on the market, it will take a significant amount of time for manufacturers to collect and present the postmarketing safety and patient acceptance data that the agency will need to determine if the products are, in fact, technically feasible alternatives (see section II.B. of this document).

II. Proposed Policy

FDA has tentatively determined that certain uses of CFC's, listed in § 2.125(e) as essential, can no longer be considered to be essential. FDA is considering proposing to remove these uses from the list of essential uses in a rulemaking to be initiated soon. Uses no longer considered essential are discussed in section II.A. of this document. FDA also expects that certain uses still considered to be essential will cease to be considered essential as new technology develops. Section II.B. of this document describes the policy that FDA has tentatively determined will be used in making determinations that these uses of CFC's are no longer essential. FDA has worked closely with EPA in developing the following policy and this ANPRM reflects those discussions. This policy will also be the subject of a notice of proposed rulemaking to incorporate the policy into FDA regulations.

A. Listed Uses That Are No Longer Considered Essential

1. Metered-Dose Steroid Human Drugs for Nasal Inhalation

Steroid human drugs for nasal inhalation are currently available using metering atomizing pumps rather than nasal MDI's. The availability of such products as Beconase® AQ and Vancenase® AQ (beclomethasone dipropionate monohydrate), Nasarel® and Nasalide® (flunisolide), Flonase® (fluticasone propionate), and Nasacort® AQ (triamcinolone acetonide), and the widespread patient acceptance of these products, indicate to FDA that using CFC's in metered-dose steroid human drugs for nasal inhalation can no longer be considered to be essential and FDA has tentatively determined to remove the use from § 2.125(e).

2. Drug Products That Are No Longer Being Marketed

Several of the essential uses listed in § 2.125(e) exempt only a single approved drug product and, in a few cases, that drug product is no longer being marketed (or is no longer being marketed in a formulation containing CFC's). FDA has tentatively determined that an essential use for which no drug product is currently being marketed should no longer be considered to be essential. The absence of a demand for the product sufficient for even one company to market it is highly indicative that the use is not essential. Therefore, FDA has tentatively determined to remove the following uses from § 2.125(e): Polymyxin B sulfate-bacitracin zinc-neomycin sulfate soluble antibiotic powder without excipients, for topical use on humans; and contraceptive vaginal foams for human use.

B. Criteria for Determination That a Use Is No Longer Essential

1. Therapeutic Classes

In evaluating petitions submitted under § 2.125(f) requesting that a new use be listed as essential, FDA has not required a showing that technically feasible non-CFC alternatives to a product contain the same active ingredient or active moiety[1] as the drug product that would be the subject of the proposed essential use. Thus, if other drug products, containing other active moieties, are available for treatment of the same condition, they may be considered technically feasible alternatives to the proposed essential-use product. Many of the drug products marketed under § 2.125 are pharmacologically closely related, are indicated for the treatment of the same conditions, and may be considered to be treatment alternatives. In evaluating whether a use remains essential, FDA believes that it is appropriate to evaluate these treatment alternatives together as a therapeutic class. In this regard, FDA has tentatively determined that metered-dose corticosteroid human drugs for oral inhalation and metered-dose short-

[1] 21 CFR 314.108(a) defines active moiety as meaning ''the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the physiological or pharmacological action of the drug substance.''

acting adrenergic bronchodilator human drugs for oral inhalation are appropriate therapeutic classes for essential-use determinations. The determination of whether drug products that are not members of either therapeutic class represent essential uses of CFC's will be made under the criteria set out in section II.B.2. of this document.

FDA has tentatively determined that all drugs currently marketed under § 2.125(e)(2) should be considered to be members of the therapeutic class ''metered-dose corticosteroid[2] human drugs for oral inhalation.'' These drugs contain the following active moieties:

- beclomethasone
- dexamethasone
- flunisolide
- fluticasone
- triamcinolone

FDA has tentatively determined that drugs containing the following active moieties currently marketed under § 2.125(e)(3) should be considered to be members of the therapeutic class ''metered-dose short-acting adrenergic bronchodilator human drugs for oral inhalation'':

- albuterol
- bitolterol
- isoetharine
- isoproterenol
- metaproterenol
- pirbuterol
- terbutaline

Adrenergic bronchodilator drug products containing the active moiety salmeterol are not included in the therapeutic class because of the longer duration of action and different indication of usage of salmeterol as compared to metered-dose short-acting adrenergic bronchodilator human drugs for oral inhalation. Adrenergic bronchodilator drug products containing the active moiety epinephrine are also not included in the class because epinephrine is the only active moiety used in drug products sold over-the-counter (OTC). These OTC drug products are available to patients who may not have access to prescription drugs. Therefore, FDA has tentatively determined that prescription drug products should not be considered as alternatives to drug products containing epinephrine. The determination of whether a drug product containing salmeterol or epinephrine constitutes an essential use would be considered under the criteria for an individual active moiety discussed in section II.B.2. of this document.

The use of CFC's in any drug product that is a member of a therapeutic class described above would no longer be considered essential if, for each therapeutic class:

1. Three distinct alternative products, representing at least two different active moieties, are being marketed, with the same route of delivery, for the same indication, and with approximately the same level of convenience of use as the products containing CFC's. At least two of the three alternative products must be MDI's.

2. Adequate supplies and production capacity exist for the alternative products to meet the needs of the population indicated for the therapeutic class.

3. At least 1 year of postmarketing use data for each product are available. There should be persuasive evidence of patient acceptance in the United States of each of the alternative products.

4. There is no persuasive evidence to rebut a presumption that all significant patient subpopulations are served by the alternative products.

FDA believes that making essential-use determinations for an entire class of closely related drug products will expedite the elimination of drug products that release ozone-depleting substances. FDA recognizes that there may be limited incentives to develop alternative products containing every active moiety currently marketed under essential-use exemptions. By eliminating the essential use by therapeutic class, FDA will ensure that these drugs do not remain on the market longer than necessary.

FDA also hopes that the knowledge that the essential use covering a given product may be eliminated, even though no alternative product exists containing the same active moiety as that product, may provide added incentive for the manufacturer of that product to develop an alternative product containing the same active moiety. In addition, the agency believes that requiring multiple alternative drug products containing multiple active moieties should ensure that all significant patient populations have safe and effective alternatives to CFC-containing drug products.

A discussion of the application of these criteria can be found in section II.B.3 of this document.

Under the proposed policy being considered for elimination of the essential-use status of the therapeutic classes, the essential-use status for individual members of a therapeutic class would only be eliminated when the essential-use status for the therapeutic class as a whole is eliminated. FDA recognizes that this approach may allow the essential-use status of an individual member of a therapeutic class to be retained despite the marketing of one or more technically feasible alternatives containing the same active moiety, pending elimination of the essential-use status for the therapeutic class as a whole. In addition to the policy FDA is considering for elimination of the essential-use status of the therapeutic classes described above, FDA is considering a policy for elimination of the essential-use status of individual members of a therapeutic class in advance of elimination of the essential-use status for the therapeutic class as a whole. Under this proposed policy, the essential-use status of an active moiety within a therapeutic class would be eliminated when one alternative product that contains the same active moiety is being marketed. All other elements of the policy regarding therapeutic classes would apply, including: The alternative product is delivered by the same route of administration, for the same indication, and with approximately the same level of convenience of use; there are adequate supplies and production capacity; at least 1 year of postmarketing use data are available; and there is no persuasive evidence to rebut a presumption that all significant patient subpopulations using that active moiety are served by the alternative product. Therapeutic classes would still be evaluated under the proposed therapeutic class policy, and alternative products used in the evaluation of the essential-use status of a member of the therapeutic class under the proposed additional policy would also be used in the evaluation of the class as a whole. FDA requests public comment on these approaches, and other possible approaches, for the elimination of the essential-use status of individual members of the therapeutic classes and the therapeutic classes as a whole.

2. Individual Active Moieties

In examining the essential-use status of drug products when FDA has not already made a tentative determination that a currently listed essential use can no longer be considered to be essential, or when the drug is not a member of one of the therapeutic classes described in section II.B.1. of this document, FDA will look at other drug products containing the same active moiety as possible technically feasible alternatives. The use of CFC's in any drug product that is not a member of a

[2] The active ingredients in all drug products currently marketed under the essential use for metered-dose steroid human drugs for oral inhalation are members of the subclass of substances known as corticosteroids. FDA has tentatively determined that it would be more accurate to use the more specific term corticosteroids rather than the more general term steroids to describe the therapeutic class.

therapeutic class described in section II.B.1. of this document would no longer be considered essential if:

1. One alternative product containing the same active moiety is being marketed, delivered by the same route of administration, for the same indication, and with approximately the same level of convenience of use compared to the product containing CFC's.

2. Adequate supplies and production capacity exist to meet the needs of the population indicated for the alternative drug product containing the active moiety.

3. At least 1 year of postmarketing use data for the product are available. There should be persuasive evidence of patient acceptance in the United States of the alternative product.

4. There is no persuasive evidence to rebut a presumption that all significant patient subpopulations are served by the alternative product.

A discussion of the application of these criteria can be found in section II.B.3. of this document.

Drug products marketed under the following current essential uses would generally be evaluated under the above ''individual active moieties'' criteria:

- Metered-dose ergotamine tartrate drug products administered by oral inhalation for use in humans.
- Intrarectal hydrocortisone acetate for human use.
- Anesthetic drugs for topical use on accessible mucous membranes of humans where a cannula is used for application.
- Metered-dose nitroglycerin human drugs administered to the oral cavity.
- Metered-dose cromolyn sodium human drugs administered by oral inhalation.
- Metered-dose ipratropium bromide for oral inhalation.
- Metered-dose atropine sulfate aerosol human drugs administered by oral inhalation.[3]
- Metered-dose nedocromil sodium human drugs administered by oral inhalation.
- Metered-dose ipratropium bromide and albuterol sulfate, in combination, administered by oral inhalation for human use.
- Sterile aerosol talc administered intrapleurally by thoracoscopy for human use.

[3] The evaluation of the essential use status of drug products containing atropine sulfate may be an exception to the application of the criteria set out in section II.B. of this document. Drug products containing atropine sulfate were never commercially marketed under § 2.125, but were manufactured for the U.S. Army for use by armed services personnel. The unique status of this use may require that other criteria be applied to it.

As discussed in section II.B.1. of this document, the essential-use status of drugs containing the active moieties epinephrine and salmeterol will also be evaluated under the ''individual active moieties'' criteria.

FDA requests public comment on the appropriateness of potentially eliminating such essential uses and criteria outlined here.

3. Discussion of Criteria

In arriving at the tentative criteria for evaluating the essential-use status of the two therapeutic classes, FDA has kept in mind that the MDI is the most widely accepted delivery system for administering drugs by oral inhalation for the treatment of asthma and chronic obstructive pulmonary disease. Physicians and patients value an MDI's compact size and ease of use. Because these factors are important and help ensure that patients receive appropriate medical treatment, FDA would require that at least two of the alternative products be available as an MDI. FDA is also aware that not all patients may tolerate a given drug product. Accordingly, FDA has reached the tentative conclusion that there must be products representing at least two different active moieties before FDA will consider that there are technically feasible alternatives to the therapeutic class. FDA is proposing that there be three distinct drug products. FDA wishes to ensure that there are substantial differences among the alternative products in order to give patients a wide variety of therapeutic options. Therefore, a drug product and a second generic drug product that refers to the first drug product to gain approval, under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)), would not generally be considered to be two distinct drug products for purposes of evaluating the essential-use status of the drug.

For most of the essential uses that would be evaluated under the ''individual active moieties'' criteria, there is only one product being marketed under each essential use. Therefore, requiring the availability of more than one alternative would appear to be inadvisable.

Because of their larger size and relative lack of convenience of use, FDA does not consider currently available nebulizers to be technically feasible alternatives to MDI's. Currently available delivery systems that FDA considers to be technically feasible alternatives to MDI's using CFC's are multiple-dose DPI's[4] and MDI's that do not contain CFC's. Continuing changes in technology may give FDA reason to revisit this tentative determination.

In evaluating whether adequate supplies and production capacity exist for the alternative product or products to meet the needs of the patient population indicated for drug products covered by an essential use, FDA's analyses will be flexible, but with one overarching principle: To ensure that there are no significant shortages of drug product that could harm the public health of the United States. Factors such as multiple production sites, to secure a steady supply if there is an interruption at one site, would be considered favorably in this regard.

In evaluating postmarketing use data and evidence of patient acceptance under the third criterion, FDA anticipates that it may be useful for sponsors of alternative products to conduct large postmarketing studies, preferably in the U.S. clinical practice setting, directly comparing their product which does not contain CFC's to the CFC-containing product for which it would be considered an alternative. It may also be possible for several sponsors to jointly commission a large postmarketing clinical study of their common products. In addition to the formal studies described above, manufacturers of alternative products, or other persons requesting the elimination of an essential use, may wish to submit to FDA a review of postmarketing surveillance data from FDA's MEDWATCH program, the spontaneous reporting systems of other countries, and all other available postmarketing data after a potential alternative product has been marketed in the United States for a period of 1 year. FDA has tentatively concluded that foreign data would not be considered acceptable as the sole evidence of patient acceptance, but these data will be considered in addition to U.S. postmarketing use data in cases where U.S. formulations and foreign formulations have been shown to be the same or substantially similar. The term ''patient acceptance'' here

[4] Single-dose DPI's that are currently marketed in the United States would not be considered technically feasible alternatives to MDI's using CFC's. The agency has tentatively determined that these single-dose DPI's do not approximate the convenience of MDI's because patients must carry both the single-dose DPI device and a supply of the drug. The patient must also load the device prior to each use. The comparative inconvenience of single-dose DPI's does not warrant their being considered technically feasible alternatives. The agency also believes that these single-dose DPI's have not shown adequate levels of patient acceptance.

assumes that the alternative products have adequate safety, tolerability, effectiveness, and compliance. Because information regarding patient acceptance is not routinely captured by postmarketing surveillance, such assessments should be incorporated into the proposed formal clinical studies.

In evaluating the last criterion, that there is no persuasive evidence to rebut a presumption that all significant patient subpopulations are served by the alternative product, FDA believes that there should be a strong presumption that, if the first three criteria are met, then all relevant subpopulations will be adequately served by alternative products. If FDA is not already in possession of evidence indicating the presence of a subpopulation served only by a product containing CFC's, then the burden of producing compelling scientific evidence that there is a subpopulation served only by a product containing CFC's would be placed on anyone opposing the determination that a use is no longer essential.

C. Implementation

FDA currently intends to publish a notice of proposed rulemaking after the comment period for this ANPRM closes. That proposed rule would eliminate essential uses for steroid human drugs for nasal inhalation and for drugs that are no longer marketed. The proposed rule would also codify the criteria for elimination of essential uses discussed in section II.B. of this document. FDA intends to use the preamble of the proposed rule to respond to comments on this ANPRM.

As the criteria for eliminating essential uses are met, FDA will propose elimination of essential uses for the appropriate therapeutic classes or individual active moieties. FDA intends that such proposals will be published and finalized in an expeditious manner.

FDA is aware that the proposed policy contained in this ANPRM is, to a certain degree, predicated on the assumption that drug manufacturers are aggressively developing alternatives to products containing CFC's. If this assumption is less than fully met, FDA recognizes that it may have to take an even more active role in encouraging the development of technically feasible alternatives. Furthermore, FDA contemplates reexamining the effectiveness of the policy set out in this ANPRM 1 to 3 years after the publication of the first final rule implementing the policy set out in this ANPRM. If this reexamination reveals that alternatives to CFC's are not being aggressively developed, FDA will consider eliminating essential uses where manufacturers of drug products covered by those uses have not demonstrated due diligence in developing alternative products.

D. Analysis of Impacts

FDA is required to examine the impacts of its proposed rules under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 Regulatory Flexibility Act requires agencies to analyze regulatory options if the proposed rule is expected to have a significant impact on a substantial number of small entities. FDA is soliciting information and data to help it examine the impacts that a proposed rule based on this advance notice would have. In order to help the agency prepare these analysis, FDA requests comments on the following impact questions:

1. Are the incentives discussed in the ANPRM adequate to spur the needed market innovation? Are there alternative means of introducing appropriate market incentives?

2. Assuming that an alternative product is approved for marketing, what is the estimated cost of obtaining postmarketing data supporting the new product as a technologically feasible alternative? How much time would be necessary? What other costs should the agency consider?

3. How much would it cost to obtain the data including the postmarketing study discussed in the ANPRM? How much would it cost to obtain the data excluding such a postmarketing study? What are the components of this estimate (e.g., person-hours, contract dollars, etc.)?

4. How much time should be allowed for phasing out a CFC-containing product no longer considered essential?

5. Are there other alternative policies that the agency should consider that would achieve the stated goals and be less burdensome to patients that use these products and/or to the industry that provides the products?

III. Other Rulemaking Proceedings Regarding CFC's

In the very near future, FDA intends to propose a rule regarding criteria to be applied in agency determinations to add new essential uses to § 2.125(e). The agency is not soliciting comments on this separate rulemaking proceeding, and is only mentioning the matter here to provide a more complete picture of FDA's current plans regarding the regulation of CFC-containing drug products. FDA does not intend to respond to any comments regarding this issue at this time; those persons wishing to comment on this issue should wait until the proposed rule is published.

Consistent with the phaseout provisions of the Clean Air Act, the proposed rule regarding the addition of new essential uses will provide new and substantially more stringent criteria for determining that a use is essential. Specific criteria will be proposed for both investigational drugs and commercially marketed drugs.

FDA currently intends that this proposed rule will provide a restructuring of § 2.125(e) to eliminate essential uses that cover an entire class of drugs, such as current § 2.125(e)(3) ''metered-dose adrenergic bronchodilator human drugs for oral inhalation.'' In their place, FDA will propose to list the use of every active moiety currently marketed under the current class essential use. This will mean that an individual wishing to market, for example, an adrenergic bronchodilator where the active moiety is not listed will need to petition FDA to amend § 2.125(e) to add the use of the active moiety.

The proposed rule would also eliminate out-of-date transitional provisions, and make other similar nonsubstantive housekeeping changes.

The agency has determined to go directly to a proposed rule on these provisions of the agency's policy, rather than requesting comment on them in this or another ANPRM, in order to accelerate consideration of the new more stringent criteria for determining when new uses are essential. FDA believes that as the agency will soon be eliminating essential uses, it would be a waste of scarce agency resources, as well as inconsistent with the general policy favoring the phase out of ozone-depleting substances, to create new essential uses unless an extraordinary showing of public benefit can be made.

Interested persons may, on or before May 5, 1997, submit to the Dockets Management Branch (address above) written comments regarding this ANPRM. 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 may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 28, 1997.
William B. Schultz,
Deputy Commissioner for Policy
[FR Doc. 97–5495 Filed 3–5–97; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Chapter I

[Docket No. FR–4170–N–07]

Native American Housing Assistance and Self-Determination Negotiated Rulemaking Committee; Meetings

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of Negotiated Rulemaking Committee Meetings.

SUMMARY: This notice announces three series of negotiated rulemaking meetings sponsored by HUD to develop the regulations necessary to carry out the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA) (Pub. L. 104–330, approved October 26, 1996).

DATES: The meetings will be held on:

1. March 20, 21, 22, 24, 25, 26, and 27, 1997.
2. April 8, 9, 10, and 11, 1997.
3. April 24, 25, 26, 28, 29, 30, and May 1, 1997.

The meetings will begin at approximately 9:00 am and end at approximately 5:00 pm on each day, local time.

ADDRESS: The meetings will be held at the Cheyenne Mountain Conference Resort, 325 Broadmoor Valley Road, Colorado Springs, CO 8096; telephone (719) 576–4600 or 1–800–588–6532; fax (719) 576–4711 (With the exception of the ''800'' telephone number, these are not toll-free numbers).

FOR FURTHER INFORMATION CONTACT: Dominic Nessi, Deputy Assistant Secretary for Native American Programs, Department of Housing and Urban Development, 1999 Broadway, Suite 3390, Denver, CO; telephone (303) 675–1600 (voice) or 1–800–877–8339 (TTY for speech or hearing impaired individuals) (With the exception of the ''800'' number, these are not toll-free numbers).

SUPPLEMENTARY INFORMATION: The Secretary of HUD has established the Native American Housing Assistance & Self-Determination Negotiated Rulemaking Committee (Committee) to negotiate and develop a proposed rule implementing NAHASDA. HUD will hold three series of meetings during March and April 1997 in Colorado Springs, Colorado to discuss the regulatory implementation of NAHASDA. The meetings will be held on the following dates:

1. March 20, 21, 22, 24, 25, 26, and 27, 1997.
2. April 8, 9, 10, and 11, 1997.
3. April 24, 25, 26, 28, 29, 30, and May 1, 1997.

The agenda planned for the meetings includes: (1) the development of regulatory language by workgroups; (2) discussion and approval of the draft regulatory language by the full Committee; and (3) other agenda items which may be agreed upon by the Committee.

The meetings will be open to the public without advance registration. Public attendance may be limited to the space available. Members of the public may make statements during the meeting, to the extent time permits, and file written statements with the Committee for its consideration. Written statements should be submitted to the address listed in the **FOR FURTHER INFORMATION** section of this notice. Summaries of Committee meetings will be available for public inspection and copying at the same address.

The location and dates of any future meetings will be published in the Federal Register. HUD will make every effort to publish such notice at least 15 calendar days prior to each meeting.

Dated: March 3, 1997.
Kevin Emanuel Marchman,
Acting Assistant Secretary for Public and Indian Housing.
[FR Doc. 97–5564 Filed 3–5–97; 8:45 am]
BILLING CODE 4210–33–P

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 202 and 206

RIN 1010–AB57

Amendments to Gas Valuation Regulations for Indian Leases

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of meeting and reopening of public comment period.

SUMMARY: The Minerals Management Service (MMS) is reopening the public comment period for a proposed rule published in the Federal Register on September 23, 1996, 61 FR 49894, amending its regulations governing the valuation for royalty purposes of natural gas produced from Indian leases.

DATES: Comments must be submitted on or before April 4, 1997. The committee meeting will be on March 26, 1997.

ADDRESSES: MMS will hold a meeting of the Indian Gas Valuation Negotiated rulemaking committee on March 26, 1997, in the conference room at: Golden Hill Office Complex, 12600 West Colfax Avenue, Suite B200, Golden, Colorado.

Written comments, suggestions, or objections regarding this proposed amendment should be sent to the following addresses. For comments sent via the U.S. Postal Service use: Minerals Management Service, Royalty Management Program, Rules and Publications Staff, P.O. Box 25165, MS 3101, Denver, Colorado 80225–0165.

For comments via courier or overnight delivery service use: Minerals Management Service, Royalty Management Program, Rules and Publications Staff, MS 3101, Building 85, Denver Federal Center, Room A–212, Denver, Colorado 80225–0165.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Publications Staff, phone (303) 231–3432, FAX (303) 231–3194, e-Mail David__Guzy@smtp.mms.gov.

FOR FURTHER INFORMATION CONTACT: David S. Guzy, Chief, Rules and Procedures Staff, at (303) 231–3432.

I. SUPPLEMENTARY INFORMATION:

Background

On September 23, 1996, MMS published a notice of proposed rulemaking in the Federal Register (61 FR 49894) to amend the valuation regulations for gas production from Indian leases. The framework for the proposed rule was the product of an Indian Gas Valuation Negotiated Rulemaking Committee. The proposed rulemaking provided for a 60-day comment period, which ended November 22, 1996, and was extended to December 3, 1996, by a Federal Register Notice (61 FR 59849, November 25, 1996). during the public comment period MMS received 13 written comments: 7 responses from industry, 4 from industry trade groups or associations, 1 from an Indian tribe, and 1 from an Indian agency. A public hearing was held in Oklahoma City, Oklahoma, on October 23, 1996.

II. Comments on Proposed Rule

MMS proposed to revise the current regulations regarding the valuation of gas production from Indian leases to accomplish the following:

- To ensure that Indian mineral lessors receive the maximum revenues from mineral resources on their land consistent with the Secretary of the