SUMMARY: The Food and Drug Administration (FDA) has determined that albuterol sulfate inhalation solution 0.5% (Ventolin) was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for albuterol sulfate inhalation solution 0.5%.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)). FDA may not approve an ANDA that does not refer to a listed drug.

Albuterol sulfate inhalation solution 0.5% is the subject of NDA 19–269 held by GlaxoSmithKline. Albuterol sulfate inhalation solution 0.5% is indicated for the relief of bronchospasm in patients with reversible obstructive airway disease and acute attacks of bronchospasm.

On February 1, 2002, Nephron Pharmaceuticals Corp. submitted a citizen petition (Docket No. 02P–0057) under 21 CFR 10.30 to FDA requesting that the agency determine whether albuterol sulfate inhalation solution 0.5% was withdrawn from sale for reasons of safety or effectiveness. The agency has determined that albuterol sulfate inhalation solution 0.5% was not withdrawn for reasons of safety or effectiveness. In support of that finding, we note that GlaxoSmithKline notified the agency in July 2001 that albuterol sulfate inhalation solution 0.5% was being withdrawn from sale because of a decline in sales. FDA has independently evaluated relevant literature and data for adverse event reports and has found no information that would indicate that this product was withdrawn for reasons of safety or effectiveness.

After considering the citizen petition and reviewing its records, FDA determines that, for reasons outlined previously, albuterol sulfate inhalation solution 0.5% was not withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list albuterol sulfate inhalation solution 0.5% in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued for reasons other than safety or effectiveness. ANDAs that refer to albuterol sulfate inhalation solution 0.5% may be approved by the agency.

Dated: March 28, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–8264 Filed 4–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0118]

Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86–10); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Guidance for FDA Staff on Sampling or Detention Without Physical Examination of Decorative Contact Lenses (Import Alert #86–10).'' The guidance document includes FDA's guidance to FDA district offices for sampling or detention without physical examination of plano (zero-powered or noncorrective) contact lenses intended solely to change the appearance of the normal eye in decorative fashion, when these products are presented for importation into the United States.

DATES: Submit written or electronic comments on the guidance by June 3, 2003.

ADDRESSES: Submit written requests for single copies of the Import Alert #86–10, to the Division of Import Operations and Policy (HFC–170), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. You may fax your request to 301–594–0413. Submit written comments on this guidance 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. See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Thaddeus J. Poplawski, Division of Import Operations and Policy (HFC–170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6553.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has been receiving reports that certain commercial entities are planning to distribute or may already be distributing plano (zero-powered or noncorrective) contact lenses intended solely to change the normal appearance of the eye in decorative fashion (decorative contact lenses). FDA understands that these products are intended to be distributed without a prescription, without fitting by a qualified eye care professional, and without ongoing professional supervision.

FDA believes that, like other contact lenses, decorative contact lenses can cause a variety of eye injuries and conditions. Lens wear has been associated with corneal ulcer, for example, which can progress rapidly, leading to internal ocular infection if left untreated. Uncontrolled infection

can lead to corneal scarring, which can lead to vision impairment. In extreme cases, corneal ulcer can result in blindness and eye loss. Other risks include conjunctivitis; corneal edema; allergic reaction; abrasion from poor lens fit; and reduction in visual acuity, contrast sensitivity, and other visual functions, resulting in interference with driving and other activities.

FDA believes that these risks cannot be sufficiently controlled unless: (1) The wearer obtains advice from an eye care professional; (2) the lenses are fitted by or under the supervision of such a professional; and (3) the wearer remains under appropriate professional supervision. Eye care professional involvement is legally required (21 CFR 801.109) for contact lenses intended for medical purposes (i.e., prosthetic use or vision correction). These products are regulated by FDA as medical devices under the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*). [1] Such control is not available for decorative contact lenses because these products are cosmetics under section 201(i) of the act (21 U.S.C. 321(i)).

Section 201(i) of the act defines ''cosmetic'' to include ''articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance * * * '' (21 U.S.C. 321(i)(1)). Decorative contact lenses are articles intended to be introduced into the eye, which is a part of the body, to beautify the wearer, promote the attractiveness of the wearer, or alter the wearer's appearance. They are claimed to achieve this cosmetic result by changing the apparent color of the iris; by appearing to add a design to the iris (e.g., a professional sports team insignia); or by imparting a nonhuman or otherwise nonnormal appearance to the eye (e.g., cat's eye). Provided they are not marketed with claims[2] that they effect physical or physiological change, decorative contact lenses are properly regulated as cosmetics under the act (cf. *United States* v. *An Article* * * * ''*Sudden Change*,'' 409 F.2d 734 (2d Cir. 1969) (''claiming to affect the structure of the skin in some physiological way'' makes a product a ''drug''); 21 CFR 700.35 (''sunscreen'' claims make a product a drug)).

The fact that contact lenses are ''devices'' in the colloquial sense does not preclude cosmetic status under the act. FDA has previously determined that section 201(i) of the act applies to appearance-enhancing devices such as wigs, hair brushes, stockings and toothpicks (Refs. 1 through 3).

Moreover, the fact that a product is intended to come into contact with the eye does not make it ineligible for cosmetic regulation (Ref. 4). Indeed, the legislative history accompanying the original 1938 act demonstrates that Congress enacted the cosmetic adulteration provisions to address the risk to users presented by cosmetic products that may cause blindness and other serious injuries (S. Rept. 74–361 at 21 (1935)).

On October 22, 2002, FDA issued Import Alert #86–10, with respect to decorative contact lenses. We are now publishing a revised Import Alert #86–10 in the **Federal Register**. The Import Alert #86–10 does not cover contact lenses that are intended for vision correction or for prosthetic or other medical use.

Section 801(a) of the act (21 U.S.C. 381(a)) authorizes FDA to refuse admission to articles that appear to be adulterated or misbranded. Based on the available evidence, FDA believes that decorative contact lenses presented for importation may appear to be adulterated under section 601(a) of the act (21 U.S.C. 361(a)), in that they contain a deleterious substance that is dangerous to wearers of the lenses when they are put to a labeled, customary, or usual use. The deleterious substance is the matrix in which colorants are embedded. This material can cause the potentially vision-threatening eye conditions discussed previously, particularly if the wearer fails to obtain appropriate professional counseling, fitting, and ongoing supervision; if the wearer trades lenses, fails to use proper disinfection and other care techniques; or if the wearer wears lenses for longer than the recommended period. Consequently, FDA believes that decorative contact lenses appear to be adulterated under section 601(a).

Decorative contact lenses may also be subject to refusal if they appear to contain unsafe color additives (21 U.S.C. 381(a) and 361(e)). FDA understands that certain overseas manufacturers or distributors might have selected color additives for use in decorative contact lenses intended for U.S. distribution based on the fact that they have been approved by FDA for use in medical devices. To be used lawfully in decorative contact lenses, a color additive must be approved by FDA for use in eye area cosmetics. Not all color additives approved for use in medical devices have been approved for eye area use in cosmetics. Consequently, decorative contact lenses may also appear to be adulterated under section 601(e) of the act.

Finally, decorative contact lenses may be subject to refusal on the ground that they are misbranded under section 602(a) of the act (21 U.S.C. 362(a)) because their labeling is false or misleading ''in any particular.'' Under the act, labeling can be misleading by failing to disclose ''facts * * * material with respect to consequences which may result'' from use of a product under customary, usual, or labeled conditions (21 U.S.C. 321(n)). As noted previously, decorative contact lenses may cause serious health problems, including (in extreme cases) blindness. FDA believes these risks are material. If they are not disclosed in labeling, then the labeling would be misleading, and the product would appear to be misbranded under section 602(a) of the act and subject to refusal under section 801(a) of the act.

II. Guidance

FDA's district offices may sample or detain without physical examination decorative contact lenses presented for U.S. importation.

The Import Alert #86–10 applies to contact lenses that are: (1) Intended to change the appearance of the normal eye in decorative fashion; and (2) intended for distribution directly to the wearer, without the involvement of a qualified eye care professional. It does not cover contact lenses that are intended for vision correction or for prosthetic or other medical or therapeutic use and that are, therefore, properly regulated as medical devices under the act.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the sampling or detention without physical examination of decorative contact lenses that appear to be adulterated under section 601(a) and (e) of the act because they contain a deleterious substance that is harmful to users and/or contain an unapproved color additive, or appear to be misbranded under section 602(a) because their labeling is false or misleading. It does not create or confer

[1] There are some lenses currently on the market under cleared 510(k)s covering contact lenses intended for both vision correction use and for solely decorative purposes.The sponsors in these cases voluntarily included a plano lens in the range of corrective powers described in the 510(k) submissions.

[2] *American Health Prods Co.* v. *Hayes*, 574 F. Supp. 1498, 1505 (S.D.N.Y. 1983), *aff'd on other grounds*, 744 F.2d 912 (2d Cir. 1984) (The courts ''have always read the * * * statuatory definitions employing the term 'intended' to refer to specific marketing representations.'').

any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute and regulations.

This guidance is effective immediately because prior public participation is not feasible or appropriate due to the risks to the public health presented by these products.

IV. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this guidance. Such comments will be considered when determining whether to amend the current guidance. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments are available in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/ora/fiars/ora_import_ia8610.html.*

VI. References

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

1. Food and Drug Administration (FDA), Compliance Policy Guide (CPG) 7128.04 (revised August 1996) (hair brushes); (*http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg590–400.htm*).

2. FDA, CPG 7128.05 (revised September 1, 1986) (wigs); (http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg590–600.htm).

3. Hutt, Peter Barton, ''Reconciling the Legal, Medical, and Cosmetic Chemist Approach to the Definition of a 'Cosmetic,' '' *Cosmetic, Toiletry, and Fragrance Association Cosmetic Journal*'', vol. 3, 1971 (excerpted in Peter Barton Hutt & Richard A. Merrill, Food and Drug Law: Cases and Materials, p. 824–825 (2d ed. 1991)).

4. FDA, CPG 7128.03 (revised August 1996) (mascara is an eye-contact cosmetic); (*http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg590–300.htm*).

Dated: April 1, 2003.

John R. Marzilli,

Acting, Associate Commissioner for Regulatory Affairs.

[FR Doc. 03–8315 Filed 4–2–03; 11:42 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0057]

Guidance for Industry: How to Use E-mail to Submit a Protocol; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry (#107) entitled ''How to Use E-mail to Submit a Protocol.'' This guidance describes how sponsors can use e-mail to submit protocols for studies intended to be conducted in support of New Animal Drug Applications (NADAs) to the Center for Veterinary Medicine (CVM). Electronic submission is part of CVM's ongoing initiative to provide a method for paperless submissions. This guidance is intended to implement provisions of the Government Paperwork Elimination Act (GPEA).

DATES: General comments on agency guidance documents are welcome at any time.

Submit written or electronic comments on the information collection requirements by June 3, 2003.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance document 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.* Comments should be identified with the full title of the guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the collection of information requirements to the Dockets Management Branch. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth L. Parbuoni, Center for Veterinary Medicine (HFV–16), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–3845, e-mail: *eparbuon@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records and electronic signatures final regulation. This regulation, part 11 (21 CFR part 11), sets forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper. Electronic records that meet the requirements of part 11 and are identified in public docket 92S–0251 as being the type of submission the agency will accept in electronic format may be used in lieu of paper records unless paper records are specifically required. CVM has identified protocols in this public docket. The public docket is accessible on the Internet at *http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm.*

Establishing a process for acceptance of the electronic submission of protocols for studies conducted by sponsors in support of NADAs is part of CVM's ongoing initiative to provide a method for paperless submissions. Upon request, CVM reviews protocols for safety and effectiveness studies. This protocol review facilitates the animal drug review process by improving the likelihood that the study design will be relevant to NADA approval.

Currently, sponsors submit protocols to CVM in paper format. CVM is publishing this guidance to give sponsors the option to submit a protocol as an e-mail attachment via the Internet. This guidance implements provisions of the GPEA. The GPEA requires Federal agencies, by October 21, 2003, to provide: (1) For the option of the electronic maintenance, submission, or disclosure of information, if practicable, as a substitute for paper; and (2) for the use and acceptance of electronic signatures, where applicable.

In order to submit a protocol for an NADA study by e-mail, sponsors should first register and follow the general instructions in guidance #108 entitled ''How to Use E-mail to Submit Information to the Center for Veterinary Medicine.''

II. Significance of Guidance

This level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking about using e-mail to submit a protocol. The document does not create or confer any rights for or on