treating the symptoms of sleep apnea. Dr. Currier is also charged with making false claims that clinical proof establishes the efficacy of SNORenz. Further, the complaint alleges that the proposed respondent failed to disclose that the product is not intended to treat sleep apnea; that sleep apnea is a potentially life-threatening disorder characterized by loud snoring, frequent interruptions of sleep, and daytime tiredness; and that persons experiencing those symptoms should seek medical attention. In addition, the complaint alleges that, when Dr. Currier made claims about SNORenz' efficacy, he failed to have a reasonable basis for such claims consisting of an actual exercise of his represented expertise in the causes and treatment for snoring. Finally, the complaint alleges that the proposed respondent failed to disclose adequately that a material connection existed between himself and the product's manufacturer and marketer, Med Gen, Inc.

Part I of the consent order requires that Dr. Currier possess competent and reliable scientific evidence to substantiate representations that SNORenz or any other food, drug, or dietary supplement reduces or eliminates snoring or the sound of snoring; reduces or eliminates snoring or the sound of snoring for any specified period of time through a single application; or eliminates, reduces or mitigates the symptoms of sleep apnea. It also requires that Dr. Currier, when acting as an expert endorser, actually exercise his represented expertise in the form of an examination or testing at least as extensive as an expert in the field would normally conduct.

Part II of the order requires that, for any product Dr. Currier advertises that has not been shown to be effective in the treatment of sleep apnea, he must affirmatively disclose, whenever the advertisement represents that the product is effective in reducing or eliminating snoring or the sounds of snoring, a warning statement about sleep apnea and the need for physician consultation.

Part III of the order requires proposed respondent to substantiate any representation about the benefits, performance, efficacy, or safety of SNORenz or any other product, service or program. If Dr. Currier makes such representations as an expert endorser, he must possess substantiation in the form of an examination or testing at least as extensive as an expert in the field would normally conduct. Part IV prohibits false claims about scientific support for any product, service, or program. Part V requires that Dr. Currier disclose any material connection between himself and any product, program or service he endorses. Parts VI and VII of the proposed order permit proposed respondent to make certain claims for drugs or dietary supplements, respectively, that are permitted in labeling under laws and/or regulations administered by the U.S. Food and Drug Administration.

The remainder of the proposed order contains standard requirements that respondent maintain advertising and any materials relied upon as substantiation for any representation covered by substantiation requirements under the order, notify the Commission of any change in his employment, and file one or more reports detailing its compliance with the order. Part XI of the proposed order is a provision whereby the order, absent certain circumstances, terminates twenty years from the date of issuance.

The purpose of this analysis is to facilitate public comment on the proposed order, and is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

This proposed order, if issued in final form, will resolve the claims alleged in the complaint against the named respondent. It is not the Commission's intent that acceptance of this consent agreement and issuance of a final decision and order will release any claims against any unnamed persons or entities associated with the conduct described in the complaint.

By direction of the Commission.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 02–28649 Filed 11–8–02; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1540]

Draft Guidance for Industry on Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Guidance for Industry, 21 CFR Part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records.'' This draft guidance describes the agency's current thinking on issues pertaining to furnishing FDA with electronic copies of electronic records that are subject to part 11. Part 11 requires persons to employ procedures and controls for records subject to part 11 that include the ability to generate electronic copies of electronic records that are accurate, complete, and suitable for FDA inspection, review, and copying. This requirement helps ensure that electronic records and electronic signatures are trustworthy, reliable, and compatible with FDA's public health responsibilities.

DATES: Submit written or electronic comments on the draft guidance by February 10, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Compliance Information and Quality Assurance (HFC–240), Office of Enforcement, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive labels to assist that office in processing your requests.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, room 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Paul J. Motise, Office of Enforcement (HFC–240), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0383, e-mail: *pmotise@ora.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Guidance for Industry, 21 CFR part 11; Electronic Records; Electronic Signatures, Electronic Copies of Electronic Records.'' In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published a regulation providing criteria under which the agency considers electronic records and electronic signatures to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper (''part 11''). The preamble to part 11 (21 CFR part 11) stated that the agency anticipated issuing supplemental guidance documents and would afford all interested parties the opportunity to

comment on draft guidance documents. Therefore, FDA is making this draft guidance available for public comment.

The draft guidance addresses issues pertaining to providing FDA with electronic copies of electronic records subject to part 11 that are accurate, complete, and suitable for FDA inspection, review, and copying. Part 11 requires persons to be able to furnish FDA with electronic copies of electronic records that are subject to part 11. This draft guidance is intended to assist people who must meet this requirement; it may also assist FDA staff who apply part 11 to persons subject to the regulation. However, this draft guidance is not intended to address issues related to electronic records that are submitted to FDA but that are not required to be maintained.

The draft guidance provides specific information on key principles and practices on electronic copies of electronic records, and it addresses some frequently asked questions. However, it is not intended to cover every aspect of generating electronic copies of electronic records that are accurate, complete, and suitable for FDA inspection, review and copying.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on providing FDA with electronic copies of electronic records. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (*see* **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any nonelectronic 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. A copy of the draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/ohrms/dockets/dockets/dockets.htm*.

Dated: October 28, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–28551 Filed 11–8–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0011]

Medical Devices; Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA.'' This document provides recommendations for complying with the premarket notification requirements for these devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify these devices.

DATES: Submit written or electronic comments on the guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax you request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electric access to the guidance.

Submit written comments concerning this guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in the brackets in the heading of this document. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Susan Runner, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of April 5, 2002 (67 FR 16406), FDA announced the availability of this draft guidance document and invited interested persons to comment on it by July 5, 2002. Also in the **Federal Register** of April 5, 2002 (67 FR 16338), FDA proposed to classify intraoral devices used to control or treat simple snoring and/or obstructive sleep apnea into class II with this guidance document as the special control. This guidance supersedes the draft guidance entitled ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and Obstructive Sleep Apnea; Guidance for Industry and FDA.''

FDA received one comment on the draft guidance from the National Association of Dental Laboratories. We considered this comment and agree that the guidance does not change the regulatory requirements for dental laboratories. We also revised the guidance to clarify how a manufacturer may submit an abbreviated 510(k) when relying on a class II special controls guidance document.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on 510(k) submissions for intraoral devices for snoring and/or obstructive sleep apnea. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1378) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.