of location will be published. All parties are welcome to attend.

Written comments should be submitted in both hard copy and electronic form. Six hard copies of each submission should be addressed to Donald S. Clark, Office of the Secretary, Federal Trade Commission, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Submissions should be captioned ''Comments Regarding Health Care and Competition Law and Policy.'' Electronic submissions may be sent by electronic mail to *healthcare@ftc.gov.* Alternatively, electronic submissions may be filed on a 3½ inch computer disk with a label on the disk stating the name of the submitter and the name and version of the word processing program used to create the document.

FOR FURTHER INFORMATION CONTACT: David Hyman, Special Counsel, Office of General Counsel, 600 Pennsylvania Avenue, NW., Room 407, Washington, DC 20580; telephone 202–326–2622; e-mail: *dhyman@ftc.gov.* Detailed agendas for the hearings will be available on the hearing web page (accessible through the FTC home page) and through Angela Wilson, Staff Assistant, at 202–326–3190 shortly before each hearing is held.

SUPPLEMENTARY INFORMATION: As the **Federal Register** notice issued for the September 2002 workshop explained, the relationship between health care and competition law and policy has tremendous significance for the United States economy and consumer/patient welfare. The economic significance of health care is enormous and will become even more so in the coming years. Consumer/patient welfare is maximized by a health care system that efficiently delivers to Americans the services they desire.

The Commission, with its dual competition and consumer protection oversight authority, has an important role to play in maintaining an efficient health care system that satisfies consumer/patient needs. Antitrust analysis traditionally has focused on restrictions to price competition. Competition routinely takes place, however, on both price and non-price parameters. Some have suggested that antitrust enforcement has given insufficient weight to non-price competition. Others have questioned whether antitrust enforcers have the right tools with which to assess non-price competition. Some have asserted that the introduction of more competition into health care markets would improve consumer welfare. Others have responded that competition policy must co-exist with other complicated laws and policies, some of which are regulatory by necessity.

The breadth, complexity, and multi-variable nature of issues such as these has led the Commission to expand upon the September 2002 workshop, and hold these multi-day, multi-topic hearings.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 02–28648 Filed 11–8–02; 8:45 am]

BILLING CODE 6750–01–P

FEDERAL TRADE COMMISSION

[File No. 002 3211]

Robert M. Currier; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed consent agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before November 21, 2002.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159-H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov,* as prescribed below.

FOR FURTHER INFORMATION CONTACT: James Dolan or Lemuel Dowdy, FTC, Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–3292 or 326–2981.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and section 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for November 5, 2002), on the World Wide Web, at *http://www.ftc.gov/os/2002/11/index.htm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, D.C. 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: *consentagreement@ftc.gov.* Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with section 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii)).

Analysis of Proposed Consent Order To Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from Dr. Robert M. Currier (the ''proposed respondent''). This matter concerns claims Dr. Currier made infomercials for a purported anti-snoring product called SNORenz.

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

SNORenz is a dietary supplement consisting of oils and vitamins that is sprayed on the back of the throat of persons who snore. The Commission's complaint charges that Dr. Currier failed to have a reasonable basis for claims, which he made in infomercials for SNORenz, about the product's efficacy in (1) reducing or eliminating snoring or the sounds of snoring, (2) reducing or eliminating snoring or the sounds of snoring for six to eight hours, and (3)

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