

prevent Respondent AHP from unilaterally seeking relief from the court. The proviso sets forth conditions under which AHP could seek to avoid, though court action, the bar on agreements that is set forth in the core prohibition of Paragraph II of the proposed order. These conditions would not affect AHP's ability to take action that did not involve an agreement otherwise prohibited in Paragraph II.

The Commission recognizes that, outside of the class action context, final settlements between private litigants ordinarily are not scrutinized by courts. Unlike the case of a court-ordered preliminary injunction based on a stipulation of the parties (the situation addressed in Paragraph IV, discussed below), the court in the final settlement context has no express legal mandate to consider the public interest. Thus, there remains some degree of risk that an anticompetitive agreement could escape the prohibition of Paragraph II if the parties were able to persuade a court to issue their agreement as a permanent injunction. On the other hand, it is also relatively rare for courts in ordinary private litigation to issue settlement agreements as permanent injunction orders. This is likely to reduce the risk that an anticompetitive agreement would evade the order, because, as noted above, the exception to the prohibitions of Paragraph II does not arise unless the court issues a permanent injunction order. On balance, in light of all the circumstances of this proposed consent order (including that it is the first involving a challenge to a final settlement with a second ANDA filer), the Commission believes that the exception contained in Paragraph II is appropriate here.

Paragraph III prohibits agreements between an NDA holder and an ANDA filer in which the ANDA filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The Commission has previously considered this type of restraint in the context of an agreement between an NDA holder and an ANDA first filer (that is, the party possessing an unexpired right to Hatch-Waxman 180-day exclusivity), and had limited the bans in previous orders to that context. Having now considered a similar restraint in an agreement involving a later ANDA filer, the Commission believes it is appropriate to extend this prohibition to agreements between an NDA holder and any ANDA filer.

Paragraph IV addresses what are sometimes referred to as interim settlement agreements. It covers agreements that involve payment to an ANDA filer and in which the ANDA

filer agrees not to enter the market for a period of time, but the patent infringement litigation continues. AHP would be barred from entering into such interim agreements. As in Paragraph II, it extends beyond cash payments to cover the NDA holder's providing "anything of value" to the ANDA filer, and provides an exception in limited circumstances, similar to those described in connection with Paragraph II of the proposed order. Although the challenged conduct here was an agreement in connection with a final settlement of litigation, rather than an interim agreement, this provision is appropriate in light of the serious antitrust concerns raised by interim agreements and the need to impose an order to prevent recurrence of violations similar to that with which AHP is charged.

The form of notice that Respondent AHP must provide to the Commission under Paragraphs II and IV of the order is set forth in Paragraph V. In addition to supplying a copy of the proposed agreement, AHP is required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the order requires Respondent to identify, among other things, all others known by AHP to have filed an ANDA for a product containing the same chemical entities as the product at issue, as well as the court that is hearing any relevant legal proceedings involving Respondent. In addition, Respondent AHP must provide the Commission with certain documents that evaluate the proposed agreement.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The proposed order will expire in 10 years.

#### *Opportunity for Public Comment*

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the agreement. The analysis is not intended to constitute an official interpretation of the agreement, the complaint, or the

proposed consent order, or to modify their terms in any way.

By direction of the Commission, Chairman Muris not participating.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 02-4374 Filed 2-22-02; 8:45 am]

**BILLING CODE 6750-01-P**

## **FEDERAL TRADE COMMISSION**

**[File No. 992 3034]**

### **TechnoBrands, Inc., et al.; 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 March 30, 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](mailto:consentagreement@ftc.gov), as prescribed below.

**FOR FURTHER INFORMATION CONTACT:** James Dolan or Heather Hipsley, Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326-3292 or 326-3285.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 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 February 19, 2002), on the World Wide Web, at <http://>

[www.ftc.gov/os/2002/02/index.htm](http://www.ftc.gov/os/2002/02/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, DC 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 e-mail box: [consentagreement@ftc.gov](mailto: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 § 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, subject to final approval, an agreement to a proposed consent order from respondents TechnoBrands, Inc., and Charles J. Anton, individually and as president of the corporate respondent.

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.

This matter concerns practices related to the advertising, offering for sale, sale, and distribution of various products to the public, including the Hollywood 48–Hour Miracle Diet, a liquid diet; the Enforma System, a diet product combination consisting primarily of chitosan and pyruvate; the BMI Magnetic Kit, a set of magnets with purported analgesic properties; the Nisim New Hair Biofactors System, a purported hair-growth product; the Clarion Ionic Filter Ceiling Fan, an air-cleaning device; and the Sila Ionic Air Purifier, another air-cleaning device. The Commission’s complaint charges that respondents violated the Federal Trade Commission Act, 15 U.S.C. 41 *et*

*seq.*, by making numerous representations that were false and/or for which they lacked a reasonable basis of substantiation. These representations concerned: the weight loss that consumers can achieve with the Hollywood Diet and Enforma; the pain relief that can be achieved with the BMI Magnetic Kit; the effectiveness of Nisim in stopping hair loss and stimulating hair growth; the ability of the air cleaners to eliminate various pollutants from indoor space; the health benefits of using the Clarion Fan; the scientific evidence for the efficacy of some of these products; the comparative efficacy of some of these products; and the experiences of consumers and celebrities who purportedly have used some of these products.

Part I of the proposed order prohibits a representation that consumers who use the Hollywood Diet, or any substantially similar product, can lose 10 lbs. in 48 hours, unless respondents possess competent and reliable scientific evidence that substantiates the representation. In addition, Part I prohibits representations that celebrities, such as actors and actresses in popular television programs, have lost substantial weight by using the product, unless the respondents possess competent and reliable evidence that substantiates the representations.

Part II of the proposed order prohibits representations that by using Enforma, or any substantially similar product, consumers can achieve substantial weight loss, or avoid weight gain, without a restricted calorie diet or exercise, unless respondents possess competent and reliable scientific evidence that substantiates the representations.

Part III of the proposed order prohibits representations that use of the BMI Magnetic Kit, or any substantially similar product, relieves severe pain; relieves pain more effectively than other kinds of treatment; and relieves pain by enlarging blood vessels, increasing blood flow, reducing inflammation, or suppressing the body’s production of pain-causing chemicals, unless respondents possess competent and reliable scientific evidence that substantiates the representations.

Part IV of the proposed order prohibits representations that Nisim, or any substantially similar product, stops hair loss in a matter of days or stimulates hair growth as effectively as prescription products, unless respondents possess competent and reliable scientific evidence that substantiates the representations.

Part V of the proposed order prohibits representations that the Clarion Ceiling

Fan, or any substantially similar product, eliminates dust mites and pet dander from the user’s environment, or that consumers who use the product will experience relief from allergies and other respiratory problems, unless respondents possess competent and reliable scientific evidence that substantiates the representations.

Part VI of the proposed order prohibits representations that the Sila Air Purifier, or any substantially similar product, eliminates mold, mildew, bacteria, chemicals, and other pollutants from a user’s environment, unless respondents possess competent and reliable scientific evidence that substantiates the representations.

Part VII of the proposed order prohibits unsubstantiated representations about the comparative or absolute benefits, performance, or efficacy of any product or service.

Part VIII of the proposed order prohibits misrepresentations about the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part IX of the proposed order prohibits representations that any user testimonial or endorsement of a product reflects the actual experience of the user or that the user’s experience is the typical experience of members of the public using the product, unless: (1) The representation is true and substantiated by competent and reliable scientific evidence; or (2) there is a disclosure of either the generally expected results for users of the product, or that consumers should not expect to experience similar results.

Part X of the proposed order requires that respondents pay to the Federal Trade Commission the sum of \$200,000.

Part XI of the proposed order is a record keeping provision that requires the respondents to maintain certain records for three (3) years after the last date of dissemination of any representation covered by the order. These records include: (1) All advertisements and promotional materials containing the representation; (2) all materials relied upon in disseminating the representation; and (3) all evidence in respondents’ possession or control that contradicts, qualifies, or calls into question the representation or the basis for it.

Part XII of the proposed order requires distribution of the order to current and future principals, officers, directors, and managers of the corporation.

Part XIII of the proposed order requires distribution of Attachment A to the order to current and future employees, agents, and representatives having responsibilities with respect to

the advertising and sale of products to the public. Attachment A is entitled "Legal Notice" and is a summary of the injunction provisions of the proposed order.

Part XIV of the proposed order requires that the Commission be notified of any change in the corporation that might affect compliance obligations under the order. Part XV of the proposed order requires that for a period of three (3) years, the individual respondent notify the Commission of the discontinuance of his current business or employment or of his affiliation with any new business or employment involving the sale of consumer products and/or services.

Part XVI of the proposed order requires the respondents to file a compliance report with the Commission.

Part XVII of the proposed order states that, absent certain circumstance, the order will terminate twenty (20) years from the date it is issued.

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

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

[FR Doc. 02-4375 Filed 2-22-02; 8:45 am]  
BILLING CODE 6750-01-P

**GENERAL SERVICES  
ADMINISTRATION**

**Interagency Committee for Medical  
Records (ICMR); Automation of  
Medical Standard Form 519A**

**AGENCY:** Office of Communications,  
GSA.

**ACTION:** Guideline on Automating  
Medical Standard Forms.

Background: The Interagency Committee on Medical Records (ICMR) is aware of numerous activities using computer-generated medical forms, many of which are not mirror-like images of the genuine paper Standard/Optional Form. With GSA's approval the ICMR eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed and granted an exception. The committee proposed to set required fields standards and that activities developing computer-generated versions adhere to the required fields but not necessarily to the image. The ICMR

plans to review medical Standard/Optional forms which are commonly used and/or commonly computer-generated. We will identify those fields which are required, those (if any) which are optional, and the required format (if necessary). Activities may not add or delete data elements that would change the meaning of the form. This would require written approval from the ICMR. Using the process by which overprints are approved for paper Standard/Optional forms, activities may add other data entry elements to those required by the committee. With this decision, activities at the local or headquarters level should be able to develop electronic versions which meet the committee's requirements. This guideline controls the "image" or required fields but not the actual data entered into the field.

**SUMMARY:** With GSA's approval, the Interagency Committee of Medical Records (ICMR) eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed and granted an exception. The following fields must appear on the electronic version of the following form:

**ELECTRONIC ELEMENTS FOR SF 519A**

Item	Placement <sup>1</sup>
Radiologic consultation request/report. Standard Form 519A (Rev. 8/1983)(Form ID).	Top of form.
1-Medical Record .....	Bottom right corner of form.
2-Physician .....	Bottom left corner of form.
3-Radiology .....	Bottom left corner of form.
Data Entry Fields: Patient information (Text) Last name First name Middle name Medical facility Age Sex SSN (Sponsor) Ward/clinic Register No. Examination requested (Use SF 519B for multiple exams) Requested by Telephone number Location of medical records Film number Date requested Pregnant—Yes (Checkbox) Pregnant—No (No)	Above below listed items.

**ELECTRONIC ELEMENTS FOR SF  
519A—Continued**

Item	Placement <sup>1</sup>
Specific reason(s) for Request (Complaints and findings) Date of examination (Month, day, year) Date of report (Month, day, year) Date of transcription (Month, day, year) Radiologic report Signature Location of radiologic facility	

<sup>1</sup> If no specific placement, data element may be in any order.

**FOR FURTHER INFORMATION CONTACT:** CDR Katherine Ciacco Palatianos, Indian Health Service, Department of Health and Human Services, 5600 Fishers Lane, Room 6A-55, Rockville, MD 20857 or E-Mail at [kciacco@hge.ihs.gov](mailto:kciacco@hge.ihs.gov).

**DATES:** Effective February 25, 2002.

Dated: February 12, 2002.

**CDR Katherine Ciacco Palatianos,**  
*Chairperson, Interagency Committee on Medical Records.*

[FR Doc. 02-4452 Filed 2-22-02; 8:45 am]

BILLING CODE 6820-34-M

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Centers for Disease Control and  
Prevention**

[60 Day-02-28]

**Proposed Data Collections Submitted  
for Public Comment and  
Recommendations**

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call the CDC Reports Clearance Officer on (404) 639-7090.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)