extending from the 30.5-mile radius to 33.1 miles south of the VORTAC, and within 4.3 miles northeast and 4.9 miles southwest of the Grand Junction ILS localizer northwest course extending from the 30.5-mile radius to the intersection of the localizer northwest course and the Grand Junction VORTAC 318° radial.

* * * * *

Issued in Seattle, Washington, on November 12, 1998.

Glenn A. Adams III,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 98–31214 Filed 11–20–98; 8:45 am]

BILLING CODE 4910–13–M

FEDERAL TRADE COMMISSION

16 CFR Part 436

Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures

AGENCY: Federal Trade Commission.

ACTION: Grant of petition for exemption.

SUMMARY: On April 16, 1998, the Commission published a notice in the **Federal Register** soliciting comments on a petition filed by Navistar International Transportation Corporation. The Commission now grants the petition and determines that the provisions of 16 CFR Part 436 shall not apply to the advertising, offering, licensing, contracting, sale or other promotion of truck dealerships by Navistar International Transportation Corporation.

EFFECTIVE DATE: November 23, 1998.

FOR FURTHER INFORMATION CONTACT: Myra Howard, Attorney, PC–H–238, Federal Trade Commission, Washington, D.C. 20580, (202) 326–2047.

SUPPLEMENTARY INFORMATION:

Before the Federal Trade Commission

Order Granting Exemption In the Matter of a Petition for Exemption from the Trade Regulation. Rule Entitled ''Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures'' Filed by Navistar International Transportation Corporation.

On April 16, 1998, the Commission published a notice in the **Federal Register** soliciting comments on a petition filed by Navistar International Transportation Corporation (''Navistar''). Navistar manufactures heavy-duty and medium-duty trucks, truck parts, and military tractors, and enters into distributorship agreements with businesspeople throughout the United States to sell and service Navistar's trucks and parts. The petition sought an exemption, pursuant to Section 18(g) of the Federal Trade Commission Act, from coverage under the Commission's Trade Regulation Rule entitled ''Disclosure Requirements and Prohibitions Concerning Franchising and Business Opportunity Ventures'' (''Franchise Rule'').

In accordance with Section 18(g), the Commission conducted an exemption proceeding under Section 553 of the Administrative Procedure Act, 5 U.S.C. § 553, and invited public comment during a 60-day period ending June 15, 1998. No comments were received. After reviewing the petition, the Commission has concluded that the Petitioner's request should be granted.

The statutory standard for exemption requires the Commission to determine whether application of the Trade Regulation Rule to the person or class of persons seeking exemption is ''necessary to prevent the unfair or deceptive act or practice to which the rule relates.'' If not, an exemption is warranted.

The abuses that the disclosure remedy of the Franchise Rule is designed to prevent are most likely to occur, as the Statement of Basis and Purpose of the Rule notes, in sales where three factors are present:

(1) A potential investor has a relative lack of business experience and sophistication;

(2) The investor has inadequate time to review and comprehend the unique and often complex terms of the franchise agreement before making a major financial commitment; and

(3) A significant information imbalance exists in which the prospective franchisee is unable to obtain essential and relevant facts known to the franchisor about the investment.

The pre-sale disclosures required by the Franchise Rule are designed to negate the effect of any deceptive acts or practices where these conditions are present. The Rule requires franchisors to provide investors with the material information they need to make an informed investment decision in circumstances where they might otherwise lack the resources, knowledge, or ability to obtain the information, and thus protect themselves from deception.

Where the conditions that create a potential for deception in the sale of franchises are not present, however, a regulatory remedy designed to prevent deception is unnecessary. Our review of the record in this proceeding persuades us that an exemption is warranted for that reason. The Petitioner has convincingly shown that the conditions that create a potential for a pattern or practice of abuse are absent; thus, there is no likelihood of unfair or deceptive acts or practices in the appointment of its truck dealership franchises.

The petition demonstrates that potential Navistar dealers are and will continue to be a select group of highly sophisticated and experienced businesspeople; that they make very significant investments; and that they have more than adequate time to consider the dealership offer and obtain information about it before investing. We not in particular that Navistar has only about 450 dealers; that prospective Navistar dealers usually have years of experience in truck or other heavy duty equipment sales; that investment costs for Navistar dealerships are approximately $1 million; and that prospective dealers participate in an extensive application and approval process, lasting anywhere from four months to a year, during which time a good deal of information is exchanged between the parties.

As a practical matter, investments of this size and scope typically involve knowledgeable investors, the use of independent business and legal advisors, and an extended period of negotiation that generates the exchange of information necessary to ensure that investment decisions are the product of an informed assessment of the potential risks and benefits. The Commission has reviewed the potential for unfair or deceptive acts or practices in connection with the licensing of motor vehicle dealership franchises on eight prior occasions since 1980, and found no evidence or likelihood of a significant pattern or practice of abuse by any of the Petitioners. If any such evidence exists, it has not yet been brought to the Commission's attention in this or any of the prior proceedings.

Thus, both the record in this proceeding and all prior experience to date with other Franchise Rule exemptions for automobile dealerships support the conclusion that Petitioner's licensing of new truck dealers accomplishes what the Rule was intended to ensure. The conditions most likely to lead to abuses are not present in the licensing of Navistar dealerships, and the process generates sufficient information to ensure that applicants will be able to make an informed investment decision. For these reasons, the Commission finds that the application of the Franchise Rule to Petitioner's licensing of truck dealer

franchises is not necessary to prevent the unfair or deceptive acts or practices to which the Rule relates.

Accordingly, the Commission has determined that the provisions of 16 CFR Part 436 shall not apply to the advertising, offering, licensing, contracting, sale or other promotion of truck dealerships by Navistar International Transportation Corporation.

It is so ordered.

By the Commission.

Issued: November 10, 1998.

List of Subjects in 16 CFR Part 436

Trade practices and franchising.

Donald S. Clark,

Secretary.

[FR Doc. 98–31203 Filed 11–20–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 98N–0394]

RIN 0910–ZA14

Medical Devices; Investigational Device Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the Investigational Device Exemptions (IDE) regulation. The regulatory changes are intended to reflect amendments to the Federal Food, Drug, and Cosmetic Act (the act) by the FDA Modernization Act of 1997 (FDAMA). These amendments provide that the sponsor of an IDE may modify the device and/or clinical protocol, without approval of a new application or supplemental application, if the modifications meet certain criteria and if notice is provided to FDA within 5 days of making the change. The rule also defines the credible information to be used by sponsors to determine if the criteria are met.

EFFECTIVE DATE: February 22, 1999.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

Experience has shown that during the course of a clinical investigation, the sponsor of the study will often want or need to make modifications to the investigational plan, including changes to the device and/or the clinical protocol. These changes may be simple modifications, such as clarifying the instructions for use, or they may be significant changes, such as modifications to the study design or device design.

The IDE supplement regulation that has been effect since 1985 (hereinafter referred to as the ''existing regulation''), § 812.35(a) (21 CFR 812.35(a)), states in part:

> A sponsor shall: (1) Submit to FDA a supplemental application if the sponsor or an investigator proposes a change in the investigational plan that may affect its scientific soundness or the rights, safety, or welfare of subjects and (2) obtain FDA approval under § 812.30(a) of any such change, and IRB approval when the change involves the rights, safety, or welfare of subjects (see §§ 56.110 and 56.111), before implementation. * * *

Under § 812.25 *Investigational plan* (21 CFR 812.25), the investigational plan includes: (1) The purpose of the study, (2) the clinical protocol, (3) a risk analysis, (4) a description of the investigational device, (5) monitoring procedures, (6) labeling, (7) informed consent materials, and (8) institutional review board (IRB) information. Although written guidance on the types of modifications that can be made without prior FDA approval has not previously been developed, the agency has permitted changes to all parts of the investigational plan, without new or supplemental IDE application approvals, if the changes did not affect the scientific soundness of the plan or the rights, safety, or welfare of the subjects, and if such changes were reported to FDA in the upcoming annual report under § 812.150(b)(5) (21 CFR 812.150(b)(5)).

On November 21, 1997, the President signed into law FDAMA. Section 201 of FDAMA (Pub. L. 105–115) amended the act by adding new section 520(g)(6) to the act (21 U.S.C. 360j(g)(6)). Section 520(g)(6) of the act permits, upon issuance of a regulation, certain changes to be made to either the investigational device or the clinical protocol without prior FDA approval of an IDE supplement. Specifically, this section of the statute permits:

> (i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in the basic principles of operation and that are made in response to information gathered during the course of an investigation; and
>
> (ii) changes or modifications to clinical protocols that do not affect—
>
> (I) the validity of the data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;
>
> (II) the scientific soundness of an investigational plan submitted [to obtain an IDE]; or
>
> (III) the rights, safety, or welfare of the human subjects involved in the investigation.

The existing IDE regulation and the new statute both permit certain changes to be made to the investigational plan without prior agency approval. FDA views the changes and modifications allowed under section 520(g)(6) of the act as consistent with the way the agency has previously interpreted existing § 812.35(a).

Section 520(g)(6) of the act, as added by FDAMA, also specifies that the implementing rule provide that such changes or modifications may be made without prior FDA approval if the IDE sponsor determines, on the basis of credible information (as defined by the Secretary of Health and Human Services (the Secretary)) that the previous conditions are met and if the sponsor submits, not later than 5 days after making the change or modification, a notice of the change or modification. Lastly, section 520(g)(6) of the act requires that FDA issue a final regulation implementing this section no later than 1 year after the date of enactment of FDAMA.

On July 15, 1998 (63 FR 38131), FDA issued a proposal to implement section 520(g)(6) of the act. FDA provided interested persons an opportunity to comment on the proposed rule by September 28, 1998. FDA received comments from five entities; one medical device manufacturer's association, two medical device manufacturers, one law firm, and one consumer. Most of the comments stated that the proposed regulation increased the economic and regulatory burden and lacked flexibility compared to the existing regulation. FDA has revised the proposed regulation in several significant respects to address these concerns. The following is a summary of the comments and FDA's response to them.

II. Summary and Analysis of Comments and FDA's Responses

A. General Comments

1. Several comments objected to FDA's proposal because it would require that notices be submitted within 5 days of implementing protocol and device changes that had previously been