DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Ch. VII

[Docket No. 991122312–9312–01]

RIN 0694–XX12

Effects of Foreign Policy-Based Export Controls

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Request for comments on foreign policy-based export controls.

SUMMARY: The Bureau of Export Administration (BXA) is reviewing the foreign policy-based export controls in the Export Administration Regulations to determine whether they should be modified, rescinded or extended. To help make these determinations, BXA is seeking comments on how existing foreign policy-based export controls have affected exporters and the general public.

Under the provisions of section 6 of the Export Administration Act of 1979, as amended (EAA), foreign policy controls expire one year after imposition unless they are extended. The EAA requires a report to Congress whenever foreign policy-based export controls are extended. Although the Export Administration Act (EAA) expired on August 20, 1994, the President invoked the International Emergency Economic Powers Act and continued in effect the EAR, and, to the extent permitted by law, the provisions of the EAA in Executive Order 12924 of August 19, 1994, as extended by the President's notices of August 15, 1995 (60 FR 42767), August 14, 1996 (61 FR 42527), August 13, 1997 (62 FR 43629), August 13, 1998 (63 FR 44121), and August 10, 1999 (64 FR 44101, August 13, 1999). The Department of Commerce, insofar as appropriate, is following the provisions of section 6 in reviewing foreign policy-based export controls and requesting comments on such controls. Foreign Policy controls need to be extended in January 2000.

DATES: Comments must be received by December 30, 1999.

ADDRESSES: Written comments (three copies) should be sent to Frank Ruggiero, Regulatory Policy Division (Room 2096), Office of Exporter Services, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: James Lewis, Director, Office of Strategic Trade and Foreign Policy Controls, Bureau of Export Administration, Telephone: (202) 482–4196. Copies of the current Annual Foreign Policy Report to the Congress are available at our website: www.bxa.doc.gov and copies may also be requested by calling the Office of Strategic Trade.

SUPPLEMENTARY INFORMATION: The current foreign policy controls maintained by the Bureau of Export Administration (BXA) are set forth in the Export Administration Regulations (EAR), parts 742 (CCL Based Controls), 744 (End-User and End-Use Based Controls) and 746 (Embargoes and Special Country Controls). These controls apply to: high performance computers (§ 742.12); significant items (SI): hot section technology for the development, production, or overhaul of commercial aircraft engines, components, and systems (§ 742.14); encryption items (§ 742.15 and § 744.9); crime control and detection commodities (§ 742.7); specially designed implements of torture (§ 742.11); regional stability commodities and equipment (§ 742.6); equipment and related technical data used in the design, development, production, or use of missiles (§ 742.5 and § 744.3); chemical precursors and biological agents, associated equipment, technical data, and software related to the production of chemical and biological agents (§ 742.2 and § 744.4); activities of U.S. persons in transactions related to missile technology or chemical or biological weapons proliferation in named countries (§ 744.6); nuclear propulsion (§ 744.5); aircraft and vessels (§ 744.7); embargoed countries (part 746); countries designated as supporters of acts of international terrorism (§§ 742.8, 742.9, 742.10, 746.2, 746.3, 746.5, and 746.7); and, Libya (§§ 744.8 and 746.4). Attention is also given in this context to the controls on nuclear-related commodities and technology (§ 744.2 and § 744.2), which are, in part, implemented under section 309(c) of the Nuclear Non Proliferation Act.

In January 1999, the Secretary of Commerce, on the recommendation of the Secretary of State, extended for one year all foreign policy controls then in effect.

To assure maximum public participation in the review process, comments are solicited on the extension or revision of the existing foreign policy controls for another year. Among the criteria considered in determining whether to continue or revise U.S. foreign policy controls are the following:

1. The likelihood that such controls will achieve the intended foreign policy purpose, in light of other factors, including the availability from other countries of the goods or technology proposed for such controls;

2. Whether the foreign policy purpose of such controls can be achieved through negotiations or other alternative means;

3. The compatibility of the controls with the foreign policy objectives of the United States and with overall United States policy toward the country subject to the controls;

4. The reaction of other countries to the extension of such controls by the United States is not likely to render the controls ineffective in achieving the intended foreign policy purpose or be counterproductive to United States foreign policy interests;

5. The comparative benefits to U.S. foreign policy objectives versus the effect of the controls on the export performance of the United States, the competitive position of the United States in the international economy, the international reputation of the United States as a supplier of goods and technology; and

6. The ability of the United States to enforce the controls effectively.

BXA is particularly interested in the experience of individual exporters in complying with the proliferation controls, with emphasis on economic impact and specific instances of business lost to foreign competitors. BXA is also interested in industry information relating to the following:

1. Information on the effect of foreign policy controls on sales of U.S. products to third countries (*i.e.,* those countries not targeted by sanctions), including the views of foreign purchasers or prospective customers regarding U.S. foreign policy controls.

2. Information on controls maintained by U.S. trade partners (*i.e.,* to what extent do they have similar controls on goods and technology on a worldwide basis or to specific destinations)?

3. Information on licensing policies or practices by our foreign trade partners which are similar to U.S. foreign policy controls, including license review criteria, use of conditions, requirements for pre and post shipment verifications (preferably supported by examples of approvals, denials and foreign regulations).

4. Suggestions for revisions to foreign policy controls that would (if there are any differences) bring them more into line with multilateral practice.

5. Comments or suggestions as to actions that would make multilateral controls more effective.

6. Information that illustrates the effect of foreign policy controls on the trade or acquisitions by intended targets of the controls.

7. Data or other information as to the effect of foreign policy controls on overall trade, either for individual firms or for individual industrial sectors.

8. Suggestions as to how to measure the effect of foreign policy controls on trade.

9. Information on the use of foreign policy controls on targeted countries, entities, or individuals.

BXA is also interested in comments relating generally to the extension or revision of existing foreign policy controls.

Parties submitting comments are asked to be as specific as possible. All comments received before the close of the comment period will be considered by BXA in reviewing the controls and developing the report to Congress.

All information relating to the notice will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, BXA requires written comments. Oral comments must be followed by written memoranda, which will also be a matter of public record and will be available for public review and copying.

The public record concerning these comments will be maintained in the Freedom of Information Records Inspection Facility, Room 6883, U.S. Department of Commerce, 14th Street and Pennsylvania Avenue, NW, Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in Part 4 of Title 15 of the Code of Federal Regulations. Information about inspection and copying of records at this facility may be obtained from the BXA Freedom of Information Officer at the above address or by calling (202) 482–0500.

Dated: November 23, 1999.

R. Roger Majak,

Assistant Secretary for Export Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. 99N–2497]

Citizen Petitions; Actions That Can be Requested by Petition; Denials, Withdrawals, and Referrals for Other Administrative Action

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations pertaining to citizen petitions. The proposal would cover citizen petition requests to issue, amend, or revoke a regulation; requests to amend or revoke an order that FDA has issued or published; or any other action specifically authorized by another FDA regulation. The document further clarifies that persons who wish to contact the agency on matters outside these three types of actions would still be able to do so through informal means, such as letters and telephone calls. In addition the proposal would also revise certain content requirements for citizen petitions and would permit FDA to refer petitions for other administrative action, seek clarification of a petitioner's requests, withdraw certain petitions, and combine petitions. These changes are intended to improve the citizen petition mechanism.

DATES: Submit written comments by February 28, 2000. Submit written comments on the information collection provisions by December 30, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., Washington, DC 20503, ATTN: Wendy Taylor, Desk Officer for FDA

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

I. Introduction

There are several mechanisms which can be used to contact FDA on a particular matter or issue. These mechanisms can be informal, such as calling the agency, sending a fax or electronic mail, writing a letter (see § 10.65(a) (21 CFR 10.65(a))), or requesting a meeting (see, e.g., § 10.65(b) and (c)). They may also be more formal, such as requesting a public hearing (see, e.g., 21 CFR 12.20) or submitting a citizen petition (see § 10.30 (21 CFR 10.30)).

Many persons use citizen petitions under § 10.30 to contact FDA on a diverse range of issues. The issues can be very specific, such as detailed scientific concerns about a particular product's safety or bioequivalence, but occasionally pertain to matters outside FDA's jurisdiction or to matters that would require legislative, rather than regulatory, relief. This results in a large number of citizen petitions filed at FDA. As of April 1999, several hundred citizen petitions have been filed and remain pending.

In many instances, it is readily apparent that citizen petitions may not be the best or most efficient mechanism for addressing the underlying subject or issue. For example, FDA often receives petitions requesting prompt or immediate action, yet each petition, after being filed and assigned to the appropriate office or center, must compete against other agency priorities, including other citizen petitions filed earlier. In contrast, a telephone call, letter, or a request for a meeting, while lacking the formal processing associated with citizen petitions, is usually an easier, faster, and more efficient way to discuss the same issue with the agency.

Reviewing and responding to these petitions can also be, and often is, a resource-intensive and time-consuming task because FDA must research the petition's subject, examine scientific, medical, legal, and sometimes economic issues, and coordinate internal agency review and clearance of the petition response. In many instances, FDA must issue a tentative response stating that the agency is unable to reach a decision on the petition within the 180-day response period established in FDA's regulations.

Questions have also arisen whether a citizen petition can be used for improper purposes, such as delaying competition (see, e.g., Noah, L., ''Sham Petitioning as a Threat to the Integrity of the Regulatory Process,'' 74 N. *Carolina L. Rev.* 1 (1995) (also noting that the Federal Trade Commission, in 1993, had concerns that petitions were being submitted to FDA for anticompetitive reasons)) or delaying agency action. Some petitioners have submitted multiple citizen petitions concerning the same subject or product