GENERAL AGREEMENT ON
TARIFFS AND TRADE

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Limited Distribution

Export of Domestically Prohibited Goods

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NOTIFICATION FROM THE UNITED STATES

Addendum

The following communication from the United States regarding the export of certain drug products is being circulated as an addendum to the information contained in document DPG/Notif.85.2.

Title III of the Omnibus Health Act on Export of Drugs

On 14 November 1986, President Reagan signed the Omnibus Health Act (S.1744) which covers a broad range of issues. Title III of the new law contains drug export provisions. Under these provisions, if the product is already authorized for investigational use by the United States Food and Drug Administration (FDA) and if the sponsor of the product is actively pursuing a FDA market approval determination (but has not yet received approval), the human or animal drug (or human biological product) concerned may be eligible for export to any of twenty-one countries listed in the Act, provided the appropriate regulatory entity of the importing country has approved the product. In addition to restricting export to the listed twenty-one countries, the new law provides for a halt in export of any drug should FDA at any time make an adverse finding concerning its health or efficacy.

Exports under the new law may take place to any of the following twenty-one countries listed in the Act: Australia, Austria, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom. As stated above, other countries can be added to this list provided stringent statutory or regulatory criteria are met.

The law also permits, under certain conditions, the export of drugs for treatment of tropical diseases to those developing countries in which such diseases are endemic, provided the safety and effectiveness of such drugs for use in the country of destination are established by credible scientific evidence.

Exporters of human and animal drugs (not yet approved in the United States) or of human biologicals (not yet licensed in the United States) must file an application for export with the Secretary of Health and Human

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Services (HHS) and receive approval from the HHS Secretary prior to first shipment. The application shall include the drug's name, the country of destination, a written agreement executed by the importer that the drug will not be transshipped to an unauthorized country, and a certification by the exporter that the drug is approved in the country of destination, that the drug has not been withdrawn from sale in such country, and that the drug meets basic quality requirements in its manufacture. (Note: Although the above text sets out the major requirements which condition export, the law does contain other conditions which must also be fulfilled before export is permitted.)

The HHS Secretary is authorized to stop export of any drug if evidence is obtained that the drug is being shipped to an unauthorized country and that such drug poses an imminent hazard to the public health of such country. (This authority would extend to stopping export of any drug being transshipped from an "authorized" country to an unauthorized country provided the imminent hazard test is met.)

Similar requirements and conditions apply to the export of unlicensed animal biologicals which are under the authority of the Secretary of Agriculture.