CHAPTER 19

SCIENTIFIC AND SURGICAL INSTRUMENTS

CHAPTER 19 - SCIENTIFIC AND SURGICAL INSTRUMENTS

INTRODUCTION

Under NAFTA, tariffs on health care products being traded between Canada, Mexico and the US will be eliminated under the various tariff reduction phase-out categories established. This should result in increased trade in this sector among the three member countries.

Over two-thirds of the Canadian instrumentation market is served by importers. Most Canadian producers specialise in only a few of the many possible types of instrumentation. The large number of small firms has resulted in a fragmented industry without clear market leaders; adapting and innovating are thus important success factors. Canadian-produced instrumentation is designed to fill niche markets. Performance is the most important purchasing factor, while price is secondary. The demand for conventional scientific instruments will continue to decline, but the need for computer-based scientific instruments and sensor systems will increase.

Canada's universal medicare system has helped support the development of an active health care products sector with strong capabilities in certain product areas. Firms in this sector are high value-added producers and many are major users of high technology inputs. The large research and development expenditures and scale of operations required for efficient production of surgical instruments means that Canadian-owned and operated production is generally small. The surgical instruments market in Canada is almost totally served by imports. Demand is expected to remain strong for disposable medical products, due largely to Canada's ageing population.

Canadian surgical instruments practices are comparable to those in the United States. Research and development techniques, clinical testing, standards and regulations, and marketing practices are similar. One difference is that the use of expensive sophisticated equipment is rationalised between hospitals, so that not every hospital has a complete range of new equipment. Further, the Canadian industry tends to be more conservative in adopting new medical technologies, slowing the commercial introduction of this equipment.

Mexico is currently updating its mandatory standards, improving enforcement and expanding conformity assessment, which means that it is expanding the number of government-accredited laboratories to test products for the Mexican market. There is strong demand in Mexico for further accreditation, creating an expanded market for laboratory and testing instruments. Mexican industry associations and chambers of

commerce also recognise change in quality standards, and this is expected to result in increased purchases of instruments.

The Mexican market for surgical instruments and supplies has increased very rapidly in the past few years, with an average 27 % annual rate. This increase may be due to the Mexican government's 1989-94 National Development Plan to provide health services to a wider population and to liberalise trade. Much of the surgical instruments used in Mexico is technologically outdated and needs to be replaced. Imports of surgical instruments are expected to continue to grow as end users increasingly buy technologically advanced and sophisticated equipment. There is little production of sophisticated surgical instruments in Mexico.

The US instrumentation industry is a diverse and technologically dynamic industry. Total shipments by these manufacturers accounted for 47.5% of world production in 1992. As cost-containment pressures dictate reliance on less-invasive surgical procedures, demand should rise most rapidly for devices used in minimally invasive surgery. As well, products used in treatment of cardiovascular disorders are in high demand. Heightened environmental concerns and the rapidly rising cost of medical waste disposal, combined with broader cost-containment pressures, have also sparked a resurgence in demand for reusable medical and surgical supplies.

An ageing population will continue to be the primary influence upon demand for surgical appliances and supplies. Cost-cutting pressures faced by hospitals and nursing homes will favour products which afford long-term care patients the opportunity for greater mobility and capacity for self-care.

CANADA

Tariffs (%)

Items:	MFN	GPT	US/Mexico
Optical	0-11.1	0-8	0-3.6
Lenses, prisms, mirrors	0-10.1	0-7.5	0-3.3
Spectacles, goggles, binoculars	0-9.2	0-6.5	0-3.9
Surveying, hydrographic, oceanographic, hydrological, meteorological, geophysical	0-9.6	0-6.5	0-3
Balances	9.2	0-6.5	0-3
Drawing, mathematical	0-12.2	0-8.5	0-3.9
Medical, surgical, dental	0	0	0
Therapy	0-10.9	0-9	0-4
Orthopaedic	0-14	0-10	0-6
X-ray, radiation	0	0	0
Materials testing	0-9.3	0-6.5	0-3
Thermometers, hydrometers, barometers, pyrometers, hygrometers, psychrometers	0-9.3	0-6.5	0-3.9
Liquid, gas measuring, checking	0-9	0-6.5	0-3.9
Physical, chemical analysis	0-9	0-6.5	0-2.2

Standards

In Canada all medical devices are subject to the requirements of Sections 3 and 19-21 of the Food and Drugs Act and Parts I-IV of the Medical Devices Regulations. It is the responsibility of the manufacturer to ensure that these requirements are met. In addition, for devices listed in Part V of the Regulations, including implanted devices, a Notice of Compliance must be obtained before such new devices are sold in Canada.

Section 14 of the Medical Devices Regulations requires the testing of all medical devices before they are offered for sale in Canada in order to demonstrate that the claimed benefits and performance characteristics are justified. The evidence of testing should be available in Canada. Please contact the Health Protection Branch, Health Canada, listed under Section III of this guide, for more information concerning the importation of these products.

This group is also regulated by the Canadian Standards Association (CSA). Any equipment that is electrical and/or uses sound or microwaves, rays, lasers, or any other

such transmissions should comply with CSA standards. Please consult with the CSA for your product's specific requirements.

Labelling

According to the Medical Devices Regulations of Canada's Food and Drugs Act, the instrument must have one or more clearly displayed labels with the following information:

- name of device;
- name and address of manufacturer, distributor, or importer;
- lot or serial number, or other means of identification by which the device may be traced;
- model designation, if applicable;
- precise nature of benefits claimed to be obtainable through use of device;
- directions for use (in both English and French if the device is available for sale at a self-service display);
- information as to whether device is sterile;
- expiration date, if applicable; and
- list of contents of the package and number of complete units contained therein.

If packaged in a pressurised disposable metal container, the product must have warning statements and symbols, as itemised in the above regulations and under the Consumer Chemicals and Containers Regulations.

The province of Quebec has additional requirements concerning all products marketed therein, which should be obtained from the Office de la Langue Francaise, found under Section III of this guide.

Packaging

There are no general packaging requirements in the Medical Devices Regulations. However, as with labelling, the manufacturer is encouraged to check for specific product requirements before sale in Canada.

For all pre-packaged products, according to the Consumer Packaging and Labelling Act and Regulations, all packages must be manufactured, constructed, or displayed in such a manner that a consumer may not reasonably be misled with respect to the quality or quantity of the product it contains. Labels on pre-packaged products must show:

- the identity and principal place of business of the person by or for whom the pre-packaged product was manufactured or produced for resale;
- the identity of the pre-packaged product in terms of its common or generic name or in terms of its function;
- such information respecting the nature, quality, age, size, material content, composition, geographic origin, performance, use or method of manufacture or production of the pre-packaged product as may be prescribed.

Questions on the Act may be directed to the Merchandise Standards Division, Industry Canada, found under Section III of this guide.

Marketing and Distribution

Canada's post-recessionary economic expansion is expected to increase expenditures on research and development, and modernisation of plant and equipment. Canadian investment will result in increased purchases of instruments. The market for these instruments in Canada is divided between industrial and institutional/commercial sectors (education, government and independent commercial laboratories).

Public responsibility for health in Canada is shared between the federal and provincial governments. At the federal level, Health Canada has overall responsibility for health care delivery. Each of the 10 provincial governments is charged with the administration of a two-part health care program covering hospitals and medical care.

There is a high degree of foreign ownership in both the distribution and manufacturing of medical equipment. Distributors outnumber manufacturers, who have established their own distribution networks in Canada. Canadian hospitals often share expensive equipment; not every hospital has a complete range of new equipment. Many provincial hospital authorities have established group purchasing arrangements. Provincial hospital associations gather annual requirements from regional hospitals and issue bids for particular products. Hospitals then place orders in accordance within the terms of the established arrangements.

The Canadian market for instruments is strongly influenced by US firms that both manufacture locally for the Canadian market and distribute US-made products. Medical products also can be marketed through Canadian distribution companies. 85% of the growing market for disposable medical and surgical products in Canada is sold to

hospitals and related institutions, 10% is sold to private clinics, and 5% is sold to extended care facilities such as nursing homes.

The latest available data suggests that the import market for surgical instruments into Canada is US $2.3 billion.

Documentation

Goods imported into Canada have mandatory documentation requirements. These are:

- Form B3, Canada Customs Coding (two copies required for an automated Customs office, three if not). It is important to fill in this form properly, especially since it is here where the importer shows the tariff treatment for his goods;
- cargo control document - manifest, waybill or other approved document that must be obtained from carrier or forwarder (two copies);
- commercial invoice, indicating the buyer and seller of the goods, price paid or payable, adequate description, including quantity, of goods contained in the shipment, together with a Canada Custom invoice containing the remaining required data (two copies), or a fully completed Canada Customs invoice, or an invoice containing all data listed by Customs.

Revenue Canada requires that certain goods imported into Canada be clearly labelled as to their country of origin, in English or French; this must be clearly located on the product. If the consumer will ultimately buy the good in a container, then it is acceptable that the container only be marked. Canadian importers are responsible for ensuring that the goods they are importing comply with the marking requirements at the time they import the goods. Please verify with a Canada Customs office concerning your product's marking requirements.

A Notice of Compliance for implanted devices and others included in Part V of the Regulations must be obtained before such new devices are sold in Canada. It may be obtained by submitting to the Director, Health Protection Branch, Health Canada, evidence of i) effectiveness; ii) safety; and iii) drafts of all labels and package inserts to be used in connection with the device.

Evidence of testing of medical devices must be available in Canada.

A signed Notification form must be submitted to the Director, Medical Devices Bureau, within ten (10) days of first sale in Canada.

Trade Associations

Canadian Laboratory Suppliers Association
Scarborough, Ontario Tel. (416) 756-3295
Medical Devices Canada
Etobicoke, Ontario Tel. (416) 620-1915
Fax. (416) 620-1595

Pan American Implant Association
Montreal, Quebec Tel. (514) 735-1133
Fax (514) 731-0651

Trade Fairs

Canadian Society of Laboratory Technologists
June
Ottawa

Healthcare
November
Winnipeg

HOPITEX-Health Care Show
May
Montreal

Med Tech
November
London, Ontario

Ontario Dental Association Annual Spring Meeting
May
Toronto

Ontario Hospital Association Exhibition
November
Toronto

Royal College of Physicians and Surgeons Meeting
September
Various

World Trade
October
Toronto

MEXICO

Tariffs (%)

Items:	General	US/Canada
Optical	5/10/15	A
Spectacles, goggles, binoculars	10/15	A
Surveying, hydrographic, oceanographic, hydrological, meteorological, geophysical	10/15/20	A
Balances	10	A
Drawing, mathematical	10/15/20	A/C
Medical, surgical, dental	10/15/20	A/B
Therapy	10/15	A
Orthopaedic	10	A
X-ray, radiation	10	A/C
Materials testing	10	A
Thermometers, hydrometers, barometers, pyrometers, hygrometers, psychrometers	10/15/20	A/B/C
Liquid, gas measuring, checking	10/15/20	A/B/C
Physical, chemical analysis	10	A

A - duties fully eliminated on January 1, 1994
B - duties removed in five equal stages of 20% annually to full elimination by 1998
C - duties removed in ten equal stages of 10% annually to full elimination by 2003

Standards

Instruments are subject to Mexican calibration requirements, as well as electrical, safety and health standards, where appropriate.

There are voluntary standards applicable to this sector, as found in SECOFI's Catalogue of Official Mexican Standards, Volume I, Classification BB. A sampling of the range of standards applicable to this sector include sterility test methods, specifications for products, and other standards. Some instruments may also be subject to a standards certification requirement by the Direccion General de Normas at SECOFI before it is eligible to be imported into Mexico. There are other requirements to be met on the importation of scientific and surgical instruments, as required by the Mexican Department of Health's Directorate for the Control of Health Inputs ("Direccion General de Control

de Insumos para la Salud"). The exporter is strongly urged to contact the Direccion General de Normas at SECOFI, the relevant Mexican sector association, or a knowledgeable Mexican importer, about the most current mandatory and voluntary standards applicable to his product.

Labelling

There are special labelling regulations on medical equipment and supplies. For more information contact the Department of Health, found under Section III of this guide.

According to Mexico's Ley de Proteccion al Consumidor (consumer protection law), all information contained on a consumer product or its labels, containers and packages must be in Spanish. These labelling requirements will be enforced at the border, meaning that compliance is effectively the responsibility of the exporter. Full original Spanish labelling is to be affixed at the point of origin.

Labels must contain specific information such as:

- name of the product or good (including a product description, if not described in the name of the product or good);
- name or trade name and address of the importer and exporter (this information may be displayed on a separate label and may be added after importation);
- country of origin of the product;
- net contents in accordance with Official Mexican Standard NOM 030-SCFI-1993;
- warnings or precautions in the case of dangerous products; and
- instructions for use, handling, and assembly of the product, if applicable (instructions may be on the label or in a separate booklet, and there must be a notice advising the consumer to read the instructions; instructions for use and assembly must be in Spanish).

When used, warranties have to be in accordance with the above Ley, specifying the location of service centres in Mexico. During the term of warranties, manufacturers or importers are required to replace "any damaged piece or component" free of charge. Instructions, manuals and warranties must be "incorporated to the product" before sale, but they will not be required for customs clearance.

The labels must be legible. The label will normally be affixed to each individual package offered for sale to consumers.

If the product is subject to a prior authorisation requirement by the Department of Health, the label of every registered product must have the legend "Aceptado S.S.A. No. .....", followed by the number of the corresponding license. Please confirm with the Department of Health for specific labelling requirements for your product.

Packaging

There are no official packaging requirements for imported products to Mexico. Please check with your Mexican broker or importer for developments in this area.

Marketing and Distribution

Mexico's updating of standards, improving enforcement and expanding conformity assessment, will result in expanding the number of government-accredited laboratories to test products for the Mexican market. There is strong demand in Mexico for further accreditation, creating an expanded market for laboratory and testing equipment. The private sector's associations also recognise change in quality standards, and this is expected to result in increased purchases of instruments. Major end-users of instruments are the medical, pharmaceutical, and food-processing industries, as well as research centres.

The largest purchasers of medical equipment are the Ministry of Health, the Mexican Social Institute, and a number of other Mexican Government decentralised agencies. Public-sector hospitals, providing 80 % of medical services in Mexico, are the most important procurers for the medical equipment industry. The most important competitive factors affecting medical equipment sales in Mexico are leading edge technology, quality, price, financing, availability of spare parts, technical support and servicing.

When selling in Mexico, it is important that companies become familiar with local procedures. Export company representatives should visit Mexico to select a local agent or distributor familiar with methods of conducting business in Mexico. Invariably, a local resident is required when selling to Mexican government health agencies.

Documentation

Specific documentation requirements for instruments should be obtained from the Department of Health or a customs broker knowledgeable in this area.

Goods imported into Mexico must be accompanied by standard documentation, as follows:

- commercial invoice (in Spanish, if prepared in English, the Spanish translation may follow original text on invoice or translation may accompany invoice) with original and several copies;
- packing list (if more than one package shipped) with at least four copies;
- bills of lading, with one original for importer and one for customs broker; and
- special certificates (see under Standards, above).

The invoice must be complete and accurate. It must include:

- place and date of issue;
- complete name and addresses of the buyer or importer in Mexico, and the exporter;
- description of merchandise, including marks, numbers, types, and quantities;
- freight and insurance charges;
- price and total value of shipment;
- signature (manual), name, and title of exporter; and
- shipper's invoice number and customer's order number.

The invoice should be sent ahead to the importer/broker/agent, in order to obtain special permits (if necessary) if shipped by sea or land, or it should accompany goods if shipped by air.

The packing list includes:

- number of packages, and detailed list of goods in each package;
- net, gross, and legal weight of each package and total shipment, in metric units, along with volume or measurements of each package and total shipment.

The bill of lading has information such as:

- types of packages in shipment and their weights and measurements;
- names and addresses of the shipper and importer, or customs broker;
- ports of origin and destination;
- description of goods;
- list of charges, including freight;
- number of bills of lading in full set; and
- carrier's official acknowledgement of receipt on board of goods for shipment.

Trade Associations

Asociacion Mexicana de Hospitales
(Mexican hospitals association)
Mexico City Tel. (5) 574-0135/0128
Fax. (5) 574-0135

Trade Fairs

Medi-Lab
Summer (biennial)
Mexico City

Medical Congress
October/November
Monterrey

UNITED STATES

Tariffs (%)

Items:	General	GSP	CBI	Canada/Mexico
Optical	5.6-10	0	0	0-4
Lenses, prisms, mirrors	5.6-8	0	0	0-3.2
Spectacles, goggles, binoculars	0-9	0	0	0-3.6
Surveying, hydrographic, oceanographic, hydrological, meteorological, geophysical	4.9-6	0	0	0-2.4
Balances	4.9-6.6	0	0	0-2.6
Drawing, mathematical	4.9-5.8	0	0	0-2.3
Medical, surgical, dental	3.4-10	0	0	0-4
Therapy	3.7-7.9	0	0	0-3.1
Orthopaedic	3.9-9	0	0	0-3.6
X-ray, radiation	2.1-4	0	0	0-1.6
Materials testing	4.8	0	0	0-1.9
Thermometers, hydrometers, barometers, pyrometers, hygrometers, psychrometers	2.8-17	0	0	0-6.8
Liquid, gas measuring, checking	4.7-9	0	0	0
Physical, chemical analysis	3.4-10	0	0	0-4

Standards

The Food and Drug Administration (FDA) is the standards body for this sector in the United States; regulations applicable to the medical device are dictated by the class by which the device is classified, Class I, II, or III. Class I devices require the lowest level of regulation, including company registration, device listing, premarket notification, and good manufacturing practices (some devices do not require the latter two). Class II devices, have in addition to Class I requirements, special controls requirements for example, labelling, mandatory performance standards, or others). Class III devices, along with meeting the above requirements, need an approved premarket approval application. The class of the device must be known in order to see what regulations apply to it. Please refer to the FDA, listed in Section III of this guide, for detailed information.

The company responsible for the device's sale in the United States must register with the FDA, or else the device will be detained. Although foreign firms are not required to

register, they are encouraged to do so, as registering may help place the company in a more opportune position to enter the US market.

The device must be listed by generic category with the FDA before any medical device can be imported into the US. The listing data must be updated when a new device is marketed with a different classification name, the intended use changes, a product is discontinued, a discontinued product is remarketed, or any information on the listing changes. The company must then notify the FDA 90 days prior to the distribution of the device (premarket notification).

The Good Manufacturing Practices (GMP) is a quality assurance program by the US federal government, similar to ISO 9000 but stricter, with regard to after-market sales monitoring. The FDA continuously monitors information concerning problems with medical devices; manufacturers whose medical devices come under scrutiny will be investigated. The FDA inspects the operations and records of foreign manufacturers to determine GMP compliance. The GMP covers quality assurance, personnel, buildings, equipment, components, production and process controls, and packaging and labelling controls.

Some devices (Class III) must obtain Premarket Approval, a scientific screening of all relevant data pertaining to the medical device. The review time is 180 days, after which time there is written notice stating if the device is approved or denied. A detailed report must be submitted to the FDA. The Premarket Approval Manual is available from the FDA and details what must be included in the report.

Distributors or manufacturers are required by law to report to the FDA when they become aware of a device that caused or contributed to death or injury to the user. Filing a report with the FDA in response to this Medical Device Reporting (MDR) regulation is the responsibility of the distributor or professional user.

Your country may have harmonised standards with the FDA; if this is the case, the device then only needs approval from your domestic standards body. To find out whether such harmonisation with your country exists, please contact the international relations staff in the Office of Standards and Regulations at the FDA, listed in Section III of this guide.

The US Federal Communications Commission (FCC) regulates any scientific and medical equipment that emits electromagnetic energy on frequencies within the radio frequency spectrum in order to prevent harmful interference. Its regulations set for conditions under which the equipment may be operated. For more information, please contact the FCC, found in Section III of this guide.

If your product has electrical elements, please also check with Underwriters Laboratories, listed under Section III of this guide, for specific standards applicable.

Labelling

A requirement of US Customs is that articles entering the United states must be marked with their country of origin. Scientific and surgical instruments are to be marked by die-stamping, cast-in-the-mould lettering, etching (acid or electrolytic), engraving, or by means of metal plates which bear the prescribed marking and which are securely attached to the article in a conspicuous place by welding, screws or rivets.

The FDA also monitors labelling of medical devices. They stipulate in the Code of Federal Regulations that:

- the name and pace of business of the manufacturer, packer, or distributor should be on the package if the device is in that form;
- the net quantity of contents be clearly declared;
- the instructions for product usage are clear: the main issue is that the indications for the device are not fraudulent or unreasonable (false or misleading).

There are special requirements for specific medical devices; the manufacturer is strongly advised to check with the FDA concerning his product's full compliance with labelling requirements.

Prescription devices, medical devices having commonly known directions, in vitro diagnostic products, medical devices for processing, repackaging, or manufacturing, and those for use in teaching, law enforcement, research, and analysis are exempt from adequate directions for use. Please verify with the FDA before labelling a product for import into the US.

Those devices for which performance standards have been developed (Class II) would have to meet any label requirements imposed by the performance standard.

Packaging

An important function of packaging is to pack the product in a way to enable US Customs to examine, weigh, measure, and release the goods promptly. Therefore, show the exact quantity of each item of goods in each box or other package, put marks and numbers on each package, and show those marks on your invoice opposite the itemisation of goods contained in the corresponding package.

Marketing and Distribution

There are significant costs involved in doing business in this sector in the US: establishing a distribution network, warehousing, and insurance costs. Small manufacturers usually rely on agents or distribution networks of wholesale suppliers for US sales. These types of suppliers often sell on consignment and require a considerable volume of inventory to provide prompt delivery. Insurance costs have also risen; the increase is significant in situations where the failure of an instrument could lead to injury or environmental damage, resulting in lawsuits. Distributors often demand a high level of liability and product insurance to be paid in advance for the whole year's potential sales because of the cost involved and the difficulty in pursuing a foreign firm in US courts.

The trend in health care is to provide care at a lower price, due to excessively high per capita costs. This means that:

- medical equipment purchasing decisions are shifting to managed care organisations and other third party buyers;
- hospitals are getting tougher in their buying;
- more independent physicians are leasing their medical equipment, resulting in the marketing of lower cost equipment to this group of buyers.

The criteria used by retailers and wholesalers for making purchasing decisions are, in order: quality, price, service, and availability.

The major buyers of medical products are the group purchasing organisations (making 70% of medical and surgical supply purchases), hospitals, healthcare service systems (managed care and group practices), nursing homes, and home medical equipment suppliers. Since hospitals tend to buy the majority of their supplies from group purchasing organisations, and these usually purchase only from suppliers already used by member hospitals, exporters must initially sell their products to hospitals and the smaller group purchasing organisations in order to build acceptance of the product.

There are four types of distribution channels: direct sales, manufacturers representatives/sales agents, distributors, and strategic distribution alliances. Group purchasing organisations, the biggest customers in the US market, prefer to buy direct from the manufacturer (but usually only deal with companies with US sales over $25 million or are first or second in product market share). End users, such as hospitals, that purchase on their own, are moving towards consolidation of vendors, meaning that the distribution channel selected should be selling various lines/products.

The size of the import market into the United States for scientific instruments is approximately US $7.6 billion.

Documentation

Within five working days of the date of arrival of a shipment at a US port of entry, entry documents must be filed, which consist of:

- a commercial invoice, or pro forma invoice when the commercial invoice cannot be produced;
- packing lists, if appropriate;
- evidence of right to make entry (bill of lading, air waybill, shipping receipt, carrier's certificate); and
- Entry Manifest, Customs Form 7533; or Application and Special Permit for Immediate Delivery, Customs Form 3461; or other form of merchandise release required by the district director.

As noted above, these products must be marked with their country of origin.

As mentioned in the Standards section, certain documentation is required from the FDA.

To register a company with the FDA requires a "Initial Registration of Medical Devices Establishment" form, obtained from the FDA along with an information and instruction book.

The listing process requires FDA form FD 2892; only one form is required for each generic category of device. If the manufacturer has chosen a sole initial distributor, he may list the medical device on the manufacturer's behalf, as long as a copy of a letter of authorisation (in English) accompanies the form. If any information on the form changes, the listing data must be updated.

A premarket notification form, obtainable from the FDA, must be submitted for products that are new to the US market, intended uses have been changed, or the product has been modified and safety or effectiveness may be affected. Initial distributors can submit this form for a foreign manufacturer, if the manufacturer has already done so.

The premarket approval process, a necessary step to selling the device in the US requires completion of a report; a detailed manual for its completion is available from the FDA.

If the manufacturer, distributor, or importer knows of a device that caused injury or death of the user, the filing of a report in compliance with the MDR (Medical Device Reporting) regulation is required.

If your company wants to protect the device sold in the United States, it should have a Utility Patent, good for 17 years after issuance. Filing must occur within the first year of

public use or sale. The address for the Patent Trademark Office is listed in the addresses section of this guide.

For further information, or to obtain any of the FDA forms required, please contact this organisation, found under Section III of this guide.

Trade Associations

Association for the Advancement of Medical Instrumentation
Arlington, Virginia Tel. (703) 525-4890
Fax (703) 276-0793

Health Industry Distributors Association
Alexandria, Virginia Tel. (703) 549-4432
Fax (703) 549-6495

Health Industry Manufacturers Association
Washington Tel. (202) 783-8700
Fax (202) 783-8750

Health Industry Representatives Association
Mission, Kansas Tel. (913) 262-4513
Fax (913) 262-0174

Independent Medical Distributors Association
Mission, Kansas Tel. (913) 262-4510
Fax (913) 262-4510

National Association of Medical Equipment Suppliers
Alexandria, Virginia Tel (703) 836-6263

Trade Fairs

All Americas Health
May (biennial)
Tampa, Florida

American Academy of Orthopaedic Surgeons
February
Orlando, Florida

American College of Healthcare Administrators Annual Convocation
May
Various

American College of Surgeons
April/October
Various

American Hospital Association Trade Exposition
August
San Francisco

Clinical Lab Management Association
August
Minneapolis

MEDTRADE/National Home Health Care Expo
November
Atlanta

SOURCES OF INFORMATION ON THIS SECTOR

"Encyclopaedia of Associations: National Organisations of the US, Vols. I & II", Gale Research Inc. (Washington), 1994.

"Industry Profile: Instrumentation", Industry Canada, 1990.

"MEXICO Business, The Portable Encyclopaedia for Doing Business with Mexico", World Trade Press (San Rafael, California), 1994.

"NAFTA and the Health Care Products Sector", Industry Canada, 1994.

"North American Free Trade Agreement Opportunities for US Industries: NAFTA Industry Sector Reports", US Department of Commerce, International Trade Administration, 1993.

"The USA Export Marketing and Resource Guide for Canadian Medical Products Manufacturers", Department of Foreign Affairs and International Trade, 1993.