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## **Memorandum**

May 28, 2003

**TO:** Honorable Bernard Sanders  
Attention: Michael Behan

**FROM:** Blanchard Randall IV and Donna Vogt  
Domestic Social Policy Division

**SUBJECT:** **Questions Concerning the U.S. and Canadian Regulatory Systems for Approving and Distributing Prescription Drugs**

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This memorandum responds to your various questions regarding the U.S. and Canadian regulatory systems for approving and distributing prescription drugs. In keeping with your time frame, the answers to the questions are fairly general and do not address all of the detailed regulatory differences in the way pharmaceuticals are approved in the two countries. The information about Canada's drug distribution system came mostly from discussions with representatives of Canadian trade associations, pharmacy regulatory authorities, and officials of Health Canada, the nation's leading health protection agency. We used this information and compared it with our knowledge and understanding of the U.S. drug approval and distribution systems.

### **Background**

The statutory requirements for approving and marketing pharmaceutical products in the United States and Canada are in general quite similar. In the United States, the approval and marketing of prescription drugs is governed under the **Federal Food, Drug, and Cosmetic Act (FFDCA)**. The Act is enforced by the Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services.

In Canada, the marketing of pharmaceuticals is regulated under the **Food and Drugs Act**. Prescription drugs are approved and regulated by the Therapeutic Products Directorate (TPD), the arm of Health Canada responsible for assuring the safety and quality of all medicines sold in that country. These statutes in the two countries are similar in that they both require drugs to be proven safe and effective through clinical studies – and then be manufactured to strict quality standards – before they are approved and distributed for use in general medicine. Recently, in a move to improve drug safety, the Canadian health agency issued a guidance document on Commercial Importation and Exportation of Drugs in Dosage Form under the Food and Drugs Act, clarifying the requirement that drugs imported into or

fabricated in Canada for commercial use must be safe and effective and comply with all Good Manufacturing Practices (GMPs) and Establishment License (EL) requirements.<sup>1</sup>

The United States and Canada have analogous requirements for the licensing of retail pharmacies and pharmacists. In Canada, pharmacies and pharmacists are licensed under provincial or territorial law; similarly, in the United States these entities are licensed at the state level. Drug wholesalers, however, are licensed differently in the two countries. In Canada, drug wholesalers are federally licensed and regulated by Health Canada, in particular its Health Products and Food Branch Inspectorate, Establishment Licensing Unit. In the United States, drug wholesalers, like pharmacies and pharmacists, are licensed and regulated by the states.

The United States and Canada have had formal regulatory systems in place to ensure the quality of pharmaceuticals for decades. Through long-established GMPs, both countries mandate strict quality controls, testing standards, and thorough inspections to ensure the safety and efficacy of prescription drugs. In 1973, the FDA and the Canadian Department of National Health and Welfare's Health Protection Branch (now Health Canada) signed a mutual cooperation agreement allowing the agencies to exchange drug plant inspection information. In the agreement's preamble, the FDA Commissioner "noted that the two agencies for a number of years have cooperated and coordinated efforts in many ways with respect to the manufacture and distribution of pharmaceutical products." He also stated that "it is in no small measure because of this cooperation that drugs marketed in Canada and the United States are as safe and efficacious as modern science and technology will permit."<sup>2</sup> According to a former FDA official, the information that was exchanged throughout the 1970s, 1980s, and early 1990s was quite extensive.<sup>3</sup> Although this agreement remains in effect, little information has been exchanged in the last few years, in part because FDA appears to have concluded that it could not afford the money or time needed to ensure that Canada's system of inspections was equivalent to that of the United States.<sup>4</sup> Nevertheless, FDA still has to inspect foreign manufacturing plants for GMPs in order for the drug to be approved for importation.

Over the years, however, the United States and Canada have agreed to other more general accords, and working groups have been formed by the two countries (and Mexico as well) to exchange information about the regulation of products. These agreements, not the 1973 cooperative agreement, are now the official conveyance for exchanging information between the countries. In 1995, the FDA, in a Memorandum of Cooperation with Mexico and Canada, recognized that all three countries needed to work closely together to prevent safety problems in all FDA regulated products. Over the years, the information exchanged under this memorandum has served to notify officials of proposed changes in regulatory requirements. The Canada, United States, and Mexico Compliance Inspection Group

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<sup>1</sup> Health Canada, Health Products and Food Branch Inspectorate (Online), *Guidance Document on Commercial Importation and Exportation of Drugs in Dosage Form Under the Food and Drugs Act*, May 1, 2003 at [[http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/guide\\_comm\\_import\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/guide_comm_import_e.html)].

<sup>2</sup> Agreement of Cooperation Between the Canadian Department of National Health and Welfare and the Food and Drug Administration at [<http://www.fda.gov/oia/default.htm>].

<sup>3</sup> Personal Communication with Mr. Roger Williams, U.S. Pharmacopeia, Rockville, MD.

<sup>4</sup> Personal communication with Mr. Walter Batts, Office of External Affairs, Food and Drug Administration.

(CUMCIG) is another formal information exchange group, channeling information between regulatory agencies of the different countries. The group holds regularly scheduled meetings to share information about pharmaceutical products and the results of facility inspections for GMPs.<sup>5</sup>

## **The Answers to Your Questions**

### **1. How many prescription drug wholesalers and pharmacists are licensed in Canada?**

According to Health Canada's Health Products and Food Branch Inspectorate, Establishment Licensing Unit, there are approximately 80 drug wholesaling companies currently licensed to distribute pharmaceutical products in Canada. This number reflects the fact that some wholesalers are multiple license holders since they have business operations in more than one province. Subsequently, Health Canada records and lists each of these licenses as separate units.

According to the National Association of Pharmacy Regulatory Authorities (NAPRA), an umbrella trade group representing the provincial pharmacy regulatory authorities, there are 26,311 pharmacists currently licensed to practice in Canada. In addition, Canada today has 7,441 licensed community pharmacies and 869 hospital pharmacies – accredited by various licensing bodies. The community pharmacy group total includes both traditional pharmacies, and the reported 100 or so licensed on-line/mail-order pharmacies now operating in Canada.

### **2. Do Canadian regulatory authorities maintain a list of licensed pharmacies in Canada? If so, are those lists available to the U.S. Food and Drug Administration (FDA) or American consumers?**

Whether Canadian regulatory authorities maintain lists of licensed pharmacies, and whether they would make the lists readily available to FDA officials or American consumers, varies on the province or territory. According to their respective licensing registrars, for example, community pharmacies in the Yukon Territory and the Northwest Territories (NWT) are not licensed under territorial law. Instead, the few pharmacies located in these vast areas are required to have "municipal" business licences, just as any other entity doing business in the territory. In any event, the Yukon registrar intimated that she was under no legal obligation to furnish FDA with the names and addresses of the six pharmacies in her area, and suggested instead that the information could be easily found in the Yukon Yellowpages. The NWT registrar said that she could supply the FDA with the names of the six pharmacies located in her territory without a problem.

In the 10 provinces, community and hospital pharmacies are licensed under provincial law. Through a self-regulating system, provincial registrars – whose addresses and phone numbers can be accessed through NAPRA's<sup>6</sup> Web site – issue licenses to both pharmacies and pharmacists. They also maintain computerized databases with the names and addresses of all the pharmacies in the province, including the name(s) of the pharmacist(s) licensed to work at each. Though the licensing of pharmacies and pharmacists is public information in

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<sup>5</sup> Personal communication with Mr. Phillip Broadbent, Office of Legislation, Food and Drug Administration.

<sup>6</sup> National Association of Pharmacy Regulatory Authorities at [<http://www.napra.org>].

Canada, the registrars all said the information in the databases is not accessible online, mostly for privacy and security reasons. However, they said they would be quite willing to share this information with the FDA, particularly if the agency made a formal request.

**3. Must all drug manufacturers, wholesalers, distributors and pharmacists operating in Canada be licensed by the Canadian government?**

Yes, all drug manufacturers, wholesalers, distributors, and pharmacists are required to be licensed under Canadian law. Moreover, every drug manufacturing site must have an "Establishment License" and a certificate of compliance verifying that the facility is in full compliance with Canadian GMP requirements. As noted above, in general, pharmacies are licensed according to the laws of the province or territory in which they're located, whereas drug wholesalers are federally licensed and regulated under the Canadian Food and Drugs Act.

**4. Are the regulations regarding the approval, manufacture and distribution of prescription drugs in Canada comparable to those in the U.S.?**

In the United States, the FDCA requires that drugs be proven both safe and effective, and be manufactured to strict quality standards, before the FDA can approve them for marketing. Drug products sold in Canada must meet virtually the same statutory requirements. Under the Food and Drugs Act, drugs not only have to be safe and effective, they have to be manufactured to quality standards similar to those for drugs produced in the United States. Furthermore, both the FDA and Health Canada have similar procedures for reviewing and approving marketing applications for new pharmaceutical products.

In the United States, a drug company (or sponsor) seeking marketing approval for a new drug must first file an Investigational New Drug (IND) application – which includes safety data from preclinical (animal) testing – with the FDA for permission to conduct clinical (human) trials. When the clinical studies have been completed, the sponsor submits a New Drug Application (NDA), which includes all of the safety and efficacy data generated during the clinical trials. Typically, the NDA also includes detailed information about the drug's production, packaging, and official labeling. Once the NDA has been reviewed, and FDA is satisfied the drug is safe and effective for its intended medical use, the agency lets the manufacturer know by letter whether the NDA is approved, or 'approvable,' if specified issues are resolved.

Prescription drugs in Canada must go through a similar clinical testing and approval process. If preclinical animal testing shows that a new chemical entity may someday be beneficial to humans, and the pharmaceutical company wants to conduct clinical trials, it must first apply to Health Canada's Therapeutic Products Directorate (TPD). If the clinical studies confirm that the new drug is safe and effective enough to be administered to patients, the sponsor typically files a New Drug Submission with the TPD. When the Directorate is satisfied that the drug's benefits for patients exceed its potential risks, Health Canada issues a Notice of Compliance (NOC) – the official Canadian stamp of approval. All prescription drugs sold in Canada receive a unique Drug Identification Number (DIN), which allows for easy identification during commercial distribution. Currently, the United States and Canada have no mutual recognition of the other's drug identifier system.

**5. May Canadian prescription drug wholesalers, distributors or pharmacists stock, distribute, sell or otherwise handle prescription drugs that are not approved for sale on the Canadian market?**

Prescription drugs cannot be sold in Canada unless they are first approved by the Therapeutic Products Directorate (TPD) of Health Canada. Once a drug has been approved, the TPD issues a Drug Identification Number (DIN) which allows the manufacturer to market the drug in Canada. DIN numbers are assigned to all approved prescription and over-the-counter (OTC) drugs. According to the Directorate, any drug product sold without a DIN is not in compliance with Canadian law.

**6. Does the Canadian Government inspect manufacturing facilities in a manner comparable to the inspections done by the U.S. FDA of U.S. facilities? And distribution facilities?**

According to officials with the Health Products and Food Branch Inspectorate, the unit of Health Canada responsible for carrying out factory inspections, all drug manufacturing facilities in Canada must undergo regular inspections by the government. Also, in situations where manufacturing plants fail inspections, Canadian law specifies a variety of penalties depending on the severity of the infraction(s). Similar to the FDA in the United States, the Canadian government has a variety of enforcement techniques at its disposal to encourage or, if necessary, compel corrective action.

**7. Does the FDA inspect facilities abroad that produce FDA-approved prescription drugs for the U.S. market?**

The FFDCA gives FDA regulatory authority over drugs shipped in interstate commerce. As such, this authority extends to drugs that are produced in foreign manufacturing facilities and then imported into the United States. Section 704 of the act allows FDA to inspect “any factory, warehouse, or establishment in which food, **drugs**, devices, or cosmetics are manufactured, processed, packed, or held for introduction into interstate commerce or after such introduction.”<sup>7</sup> According to FDA’s Office of Regulatory Affairs, International Inspection Program, the agency has been inspecting foreign prescription and bulk drug manufacturers identified in premarketing applications since the early 1970s.<sup>8</sup> Moreover, the FDA says it has inspected foreign toxicological laboratories and other facilities involved in the pre-NDA approval testing of new drugs since 1977 to assure compliance with Good Laboratory Practices (GLPs) requirements.

**8. Do manufacturing facilities producing prescription drugs for the Canadian market have to comply with best management practices comparable to those required of facilities manufacturing products for the U.S. market? And distribution facilities?**

If the question about “best management practices” refers to “good manufacturing practices” (GMPs), both U.S. and Canadian law require pharmaceutical companies to comply with strict GMPs when manufacturing their products. According to Health Canada’s Health Products and Food Branch Inspectorate, its newly revised Good Manufacturing

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<sup>7</sup> FFDCA, Section 704(a)(1), Factory Inspection.

<sup>8</sup> Food and Drug Administration, Office of Regulatory Affairs, Inspection Reference. [[http://www.fda.gov/ora/inspect\\_ref/default.htm](http://www.fda.gov/ora/inspect_ref/default.htm)]

Practices (GMP) Guidelines issued December 31, 2002, ensure that all prescription drugs in Canada are consistently manufactured to very high quality standards.<sup>9</sup> Based on our discussions with various regulatory officials, Canada and the United States have equivalent GMPs for finished pharmaceutical products. In fact, a drug's marketing authorization in Canada largely depends on whether GMP standards were followed during the production process. Distribution facilities, which are also licensed and regulated by Health Canada, must abide by GMPs as well.

In August 2002 the FDA announced a new initiative to enhance the regulation of pharmaceutical manufacturing and product quality. According to the agency, the initiative will focus on, and reexamine, its current GMP program, and will cover veterinary and human drugs, including human biological products. Laying out three major goals, the agency said it wanted to focus its resources at those aspects of manufacturing that pose the greatest potential risks; ensure that its effort to establish and enforce drug product quality standards does not impede the introduction of new manufacturing technologies in the pharmaceutical industry; and instill more consistency and predictability in its approach to assuring production quality and safety among its centers and field components.<sup>10</sup>

### **9. Are Canadian and U.S. prescription drug labeling requirements similar? Must the labels be printed in English?**

The United States and Canada have similar laws and rules governing the labeling of prescription and OTC drugs. In general, both countries require drugs to be properly labeled before they can be shipped for commercial distribution. More important, the information contained in the label may not be false or misleading to the consumer in any way. Since Canada is officially a bi-lingual nation, warnings and safety information on prescription and OTC labeling are printed in both English and French.

Like the United States, Canadian regulations require different labeling formats for prescription and OTC drug products. For prescription drugs, the official labeling reflects the medical information derived from preclinical and clinical testing, and includes information about approved use(s), and proper dosing, as well as specific warnings about possible adverse effects. Both countries require this label to accompany the drug when and wherever it is shipped during commercial distribution. The information in this label is intended more for the health professional than the patient. Today, in both Canada and the United States, when prescription drugs are dispensed by the pharmacist, the patient can, instead, receive a computer generated leaflet describing, in layman's terms, the medical condition the drug is meant to treat, how it should be taken, and a list of common side-effects. In the case of OTC drugs, the laws of both countries require that they be labeled with information that helps consumers use the product safely, including information about possible side-effects and adequate directions for proper use.

In recent years, the FDA has taken steps to overhaul and simplify the labeling requirements for both prescription and OTC drugs in the United States. In 1999, the agency

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<sup>9</sup> Health Canada, Health Products and Food Branch Inspectorate, GMP Guidelines, 2002 Ed. Version 2, Dec. 31, 2002.

[[http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gmp\\_guidelines\\_2002\\_tc\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gmp_guidelines_2002_tc_e.html)]

<sup>10</sup> FDA Unveils New Initiative to Enhance Pharmaceutical Good Manufacturing Practices, *FDA News*, Aug. 21, 2002, at [<http://www.fda.gov/bbs/topics/NEWS/2002/NEW00829.html>].

finalized a rule requiring a new, easy-to-read, standardized format for OTC drug labeling.<sup>11</sup> In addition, the agency proposed new rules in 2000 to revise and enhance the content and labeling for prescription drugs and biological products.<sup>12</sup> It said the revised format would make it easier for health care professionals to access, read, and utilize the information conveyed in product labeling. At present, Canada has no plans to revise its rules for prescription drug labeling. However, for the past several years, Canadian officials have been working on a rule that will, when finalized, require that all inactive ingredients be included in the labeling of OTC drugs.

**10. Does the Canadian government require the maintenance of a complete chain of custody record for prescription drugs from manufacturers to distributors/wholesalers to pharmacists?**

According to Canada's Health Products and Food Branch Inspectorate, current regulatory requirements governing the distribution of prescription drugs in Canada do maintain a "chain of custody." All approved prescription drugs in Canada are assigned a specific drug identification, or DIN number. The DIN must be displayed on the main panel of the package label. Moreover, all drug wholesalers and distributors must follow certain rules and regulations that add accountability to the system. The Inspectorate information officer pointed out, for example, that all prescription drugs shipped in Canada must, by law, include the name and business address of each company involved along the chain of distribution. As such, since most of the pharmaceuticals sold and distributed in Canada originate from U.S. manufacturers, it's not unusual for a package of prescription drugs to arrive at a Canadian pharmacy with the name of the manufacture, wholesaler, and distributor all identified on the shipping label.

In the United States, the FDA uses the National Drug Code (NDC) System as the universal product identifier for human drugs. The NDC currently lists all drugs manufactured, prepared, propagated, compounded, or processed by drug establishments registered under the FDCA – including prescription and selected OTCs, insulin, and domestic, and foreign drug products that are in commercial distribution in the United States. Through the use of a 10-digit NDC number, which is printed on the label, the coding system identifies the labeler/vendor, dosage, and package size of the pharmaceutical product.<sup>13</sup> Thus, the NDC number travels with the product as it is shipped from the manufacturer to the wholesaler and then to the retail pharmacy.

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<sup>11</sup> U.S. Dept. of Health and Human Services, Food and Drug Administration, "Over-The-Counter Human Drugs; Labeling Requirements," Final Rule, *Federal Register*, v. 64, no. 51, Mar. 17, 1999, p. 13253.

<sup>12</sup> U.S. Dept. of Health and Human Services, Food and Drug Administration, Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels, Proposed Rule, *Federal Register*, v. 65, no. 247, Dec. 22, 2000, p. 81081.

<sup>13</sup> According to FDA, the term "labeler" refers to any firm that manufactures, repackages, or distributes pharmaceuticals.

**11. Are there mechanisms in Canada for monitoring and preventing counterfeits on the Canadian market that are comparable to those in places in the U.S.?**

In Canada, the risk of counterfeit pharmaceuticals is seen as a non-traditional risk imposed from the outside. Generally, Canadian health officials said they manage the risk of counterfeit drugs much like their regulatory counterparts in the United States. The government takes samples of pharmaceutical products periodically to test whether they are contaminated and/or counterfeit. According to Canadian officials, the chief mechanism for deterring counterfeit drugs is their government's relationship with the pharmaceutical industry; one that allows industry to manage and control the supply chain, while the government assists the industry with the technology and intelligence they both need to detect bogus pharmaceutical products.

Currently, in the U.S., when the FDA receives a report of a counterfeit drug, it works with consumers, manufacturers, wholesalers, distributors, and state agencies to determine the composition of the product, the extent of its distribution, and the remedial action necessary to protect the public health.

**12. Is there evidence of counterfeit drugs on the Canadian market? If so, does it suggest that there is more of a problem of counterfeits on the Canadian market than on the U.S. market?**

Canadian health officials said there is little evidence of a counterfeit drug problem in their country at this time. As for the United States, the FDA has anecdotal evidence, but little quantitative data, on the number of counterfeit drugs being produced or imported into this country. As one example, we have attached a May 23, 2003 *FDA Talk Paper* warning healthcare providers and patients about the recent recall of three lots of the cholesterol lowering drug Lipitor. The talk paper shows the agency's current approach to dealing with and removing counterfeit drugs when they are found in the distribution pipeline.<sup>14</sup>

The FDA insists that because the U.S. prescription drug production system is "closed" (i.e., all steps in the production process are tightly controlled), it can be monitored in ways that lessen the opportunity for counterfeit drugs to enter the country. Nevertheless, the agency insists there is always the risk that bogus prescriptions could be transhipped through Canada that originated in other countries. To reduce this possible risk, the FDA is in the process of designing screening criteria into their import alert system that will trigger a field analysis when there is a strong suspicion that a shipment of drugs may be counterfeit.

**13. Is there post-marketing surveillance of adverse drug reactions in Canada similar to that in the U.S.?**

The regulatory requirements for reporting adverse drug reactions (ADRs) in the United States and Canada are very much alike. Both countries employ similar postmarketing surveillance systems to monitor the unanticipated side-effects that often go unseen or detected until the drug has been taken by a larger number of patients. In Canada, the reporting of adverse drug reactions is coordinated by the Marketed Health Products Directorate of Health Canada with the assistance of five Regional Adverse Reaction

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<sup>14</sup> "FDA Alerts Consumers and Health Professionals to Recall of Counterfeit Lipitor," *FDA Talk Paper*, May 23, 2003 at [<http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01224.html>].

Reporting Centres (British Columbia, Saskatchewan, Ontario, and the Atlantic Region). In the United States, ADRs are reported to and monitored through FDA's MedWatch program.<sup>15</sup> Both countries require drug companies to report within 15 calendar days all serious adverse drug events they become aware of. Although doctors and other health care professionals in both countries are strongly encouraged to report adverse drug reactions, their participation in the surveillance process is strictly voluntary.

**14. Is there a mechanism for conducting a recall in Canada similar to that in the U.S.?**

The United States and Canada have similar mechanisms for conducting drug recalls. According to the Health Products and Food Branch Inspectorate, Health Canada has a unit that is responsible for initiating drug recalls if the need arises. Recalls are initiated when postmarket surveillance data indicate that the use of a prescription drug may be causally linked with serious, but not necessarily life-threatening side-effects. Health Canada's usual approach is to convince the manufacturer that it would be in its and the public's interest to withdraw the drug from the market voluntarily. The FDA often takes the same approach to persuade drug companies to voluntarily pull prescription drugs from the U.S. market. But, in situations where the drug's side-effects are serious enough to be life-threatening, health officials in both countries have the statutory authority to suspend the product's marketing approval immediately.

**15. What testing or other verification of the authenticity or safety of prescription drugs imported into the U.S. by prescription drug manufacturers does the U.S. FDA conduct?**

Under the Federal Food, Drug, and Cosmetic Act, only FDA approved drugs can be imported into the United States. Further, Sec. 801(d)(1) of the Act stipulates that only drug companies can legally import drugs into this country. Assuming that these approved drugs were produced in facilities controlled by the manufacturer, under a 'closed' system in compliance with current GMPs, absent probable cause, they would not undergo routine authenticity testing by the FDA before reaching the shelves of retail pharmacies. If the agency discovers, however, that substandard, unsafe, or even counterfeit pharmaceuticals are being shipped into the country, it has the authority to collect samples, inspect facilities, and/or initiate various enforcement actions to stem their further distribution. In situations where consumers 'import' prescription drugs via online mail-order pharmacies, the FDA insists that its ability to monitor the safety and quality of the drugs is significantly hampered.

**16. What testing or other verification of the authenticity or safety of prescription drug components imported into the U.S. by prescription drug manufacturers does the U.S. FDA conduct?**

In general, the FDA regulates the components used to produce prescription drugs as Bulk Pharmaceutical Chemicals (BPCs). According to an FDA inspection guidance, BPCs are made by chemical synthesis, by recombinant DNA technology, fermentation, enzymatic reactions, recovery from natural materials, or a combination of these processes.<sup>16</sup> The manufacture of BPCs – like the process for finished prescription drugs – must be carried out according to GMPs, whether they are produced here or a foreign country.

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<sup>15</sup> Food and Drug Administration, MedWatch, at [<http://www.fda.gov/medwatch/>].

<sup>16</sup> FDA Guide to the Inspection of Bulk Pharmaceuticals, May 1994, p. 2 at [[http://www.fda.gov/ora/inspect\\_ref/igs/bulk.htm](http://www.fda.gov/ora/inspect_ref/igs/bulk.htm)]

According to the guidance, domestic manufacturers of bulk pharmaceutical chemicals are required to register and must list their products with the FDA under Section 510 of the FDCA if they meet the definition of “bulk drug substance” under 21 CFR 207.3(a)(4), i.e., a substance that is intended as a drug and, when used, becomes an active ingredient or finished dosage form of such drug. Although foreign firms are not required to register, they are required by regulation to list all of their products with the agency, and products not so listed are subject to detention and/or refusal of entry.<sup>17</sup> Also, the guidance document says that the results of inspections of foreign BPC manufacturers directly affects the status of these products when they enter this country. These chemicals can be sampled, detained, and/or refused entry into the United State if an inspection of the foreign manufacturer suggests that the firm is not complying with GMPs.

**17. Does the FDA have the authority under current law to test or otherwise verify the authenticity and safety of prescription drugs brought into the U.S. by drug manufacturers or others? If so, what is the extent of the authority, i.e., does the FDA have the authority to inspect the facilities of [sic] selling prescription drugs into the U.S., such as Canadian pharmacies?**

As noted in the response to question 15, although the FDA has regulatory authority over all pharmaceutical products entering the United States, for years now the agency has said it cannot vouch for the authenticity or safety of mail-order prescription drugs purchased online from Canadian pharmacies. This is largely because as a U.S. government agency it has no legal authority over Canadian pharmacies, and therefore has no way of inspecting or assuring the quality of the pharmaceutical products dispensed from these pharmacies.

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<sup>17</sup> 21 C.F.R. 207.40(a).



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## ***FDA Talk Paper***

T03-38  
May 23, 2003

Media Inquiries: 301-827-6242  
Consumer Inquiries: 888-INFO-FDA

### **FDA Alerts Consumers and Health Professionals to Recall of Counterfeit Lipitor**

The Food and Drug Administration (FDA) today announced that Albers Medical Distributors, Inc., has voluntarily recalled three lots of 90-count bottles of the cholesterol-lowering drug Lipitor and is warning healthcare providers and others that these three lots of counterfeit Lipitor represent a potentially significant risk to consumers. The product was repackaged by Med-Pro, Inc., of Lexington, Neb., and the labels say "Repackaged by: MED-PRO, Inc. Lexington, Neb." in the lower left-hand corner.

The following lots are involved in this recall:

- 20722V - 90-tablet bottles, Expiration 09-2004
- 04132V - 90-tablet bottles, Expiration 01-2004
- 16942V - 90-tablet bottles, Expiration 09-2004

FDA is urging healthcare providers and patients alike to check the packaging very carefully before using this product. Patients who have any of the product (labeled as "Repackaged by MED-PRO, Inc.") with these three lot numbers should not take it, and they should return the product to their pharmacies.

As part of the FDA's ongoing efforts to investigate and address unscrupulous counterfeiting activities, FDA's Office of Criminal Investigations is investigating the existence of counterfeit Lipitor. Lipitor is a member of a class of cholesterol-lowering drugs that are commonly referred to as "statins."

In carrying out its public health mission, FDA regularly conducts investigations and testing to identify and remove from market products that are counterfeit, have been tampered with, or are otherwise unsuitable.

FDA supports the activities of legitimate manufacturers, in cooperation with FDA, to inform the public about counterfeit products and how to identify them. The agency is committed to rooting out counterfeiting activity and alerting the public to the existence of counterfeit product. Earlier this month, FDA entered into an agreement with a major pharmaceutical trade association to cooperate more closely on cases of suspected counterfeit products.

FDA's investigation into this matter is continuing.

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