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May 13, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Dear Sir or Madam:

On behalf of our clients, Montreal, Maine & Atlantic Railway Limited, Eastern Maine Railway Company, New Brunswick Southern Railway Company Limited and Sunbury Transport Limited, the undersigned hereby submits the enclosed document provided to officials of the Federal Food and Drug Administration regarding "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," Docket No. 2002N-0278, and asks that it be placed on the public record.

If you have any questions or require any additional information, please do not hesitate to contact the undersigned.

Sincerely,

**DLA PIPER RUDNICK GRAY CARY US LLP**

  
Andrea J. Grant,  
Counsel

**MONTREAL, MAINE & ATLANTIC RAILWAY LIMITED  
EASTERN MAINE RAILWAY COMPANY  
NEW BRUNSWICK SOUTHERN RAILWAY COMPANY LIMITED  
SUNBURY TRANSPORT LIMITED**

May 1, 2005

The Honorable John M. Taylor, III  
Associate Commissioner for Regulatory Affairs  
Office of Regulatory Affairs  
Food and Drug Administration  
Department of Health and Human Services  
Rockville, Maryland 20857

Re: Sunbury Train

Dear Mr. Taylor:

Thank you for your March 1, 2005 letter responding to our correspondence on compliance by the "Sunbury Train" with the FDA Prior Notice obligations. 21 CFR Part 1. We appreciate FDA's concern about our financial situation, the Agency's cooperation, and its willingness to consider our special case in the context of deliberations on the final rule.

As you know, because of our unique circumstances, we requested an exemption from the Prior Notice requirements and set forth a legal and policy basis on which we believe the Agency could act. In your letter, you requested that we submit our request, all correspondence and supporting documentation directly to the FDA Dockets Management Branch for consideration in the current final rulemaking process. We have now done so. The following responds to several points raised in your letter.

First, we continue to believe that the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (P.L. 107-188) (the "Bioterrorism Act") provides FDA with substantial flexibility in establishing the scope of the Prior Notice rule. FDA is certainly correct in its finding that the law does not provide for specific exemptions. However, the statute states that the new obligations will apply to food "imported or offered for import into the United States." Congress did not define or give specific guidance on that phrase. Thus, so long as FDA interprets the mandate in a reasonable manner, it may exclude certain shipments from the scope of the rule. The preamble that accompanied the Interim Final Rule acknowledges that Congress was silent on this point, and that FDA must reasonably interpret the meaning of the phrase. See Chevron USA Inc. v. NRDC cited in the Preamble.

In the instant case, food on the Sunbury Train is moving between two points in Canada via Northern Maine for a relatively short distance over a twelve-hour period. It moves pursuant

to a Customs bonded procedure known as "transportation and exportation" – a procedure that is administered by the U.S. Bureau of Customs and Border Protection. Because the Train and its cargo do not actually enter U.S. commerce, it would be reasonable and consistent with the statute and case law to exclude such shipments from the Prior Notice obligations.

Second, we believe that we are the only railroad operating between two Canadian points transiting the United States. These shipments are distinguishable from those moving from Canada to Mexico via the U.S. or vice-versa because the distance and time within the U.S. is very short. Moreover, moving products in bond and under seal pursuant to a "transportation and exportation" entry is an established practice. Customs has been supervising the transit of goods in this manner for almost 75 years. It is an agency with substantial experience in protecting U.S. borders, and in recent years, Congress has given that Bureau a major role in maintaining homeland security. Movement under this procedure should be considered low risk.

Third, as noted in our correspondence, the Interim Final Rule provides a significant exemption that should serve as a precedent for the Sunbury Train. FDA permits articles that are imported and then exported directly from the port of arrival to be excluded from the Prior Notice obligations. Those articles move under an "Immediate Export" entry. FDA found that there are existing controls that will not allow the goods to leave the port even though such goods are permitted to move among different destinations within a given port, often substantial distances – 20 to 40 miles. The same rationale applies to a "transportation and exportation" entry. There are existing controls to prevent tampering and unloading. There is essentially no difference between the two entries, and certainly no greater risk posed by the latter. Both are supervised by Customs.

Accordingly, we respectfully request that, in the final rule, FDA grant the Sunbury Train an exemption from the Prior Notice requirements. However, if the Agency declines to grant that request, we ask that the FDA accept the Automated Manifest System ("AMS") filings by shippers on the Train and deem those shippers to be in compliance with the Prior Notice obligations. In the alternative, the Agency could exempt shipments transiting the U.S., for a period not to exceed 24 hours, in bond and under seal. Any of these alternatives would constitute a reasonable interpretation of the statute.

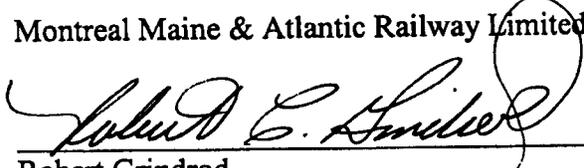
Again, we very much appreciate FDA's review and consideration of our unique circumstances.

Sincerely,

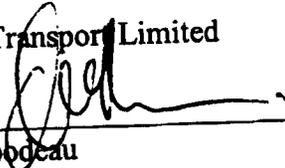
Eastern Main Railway Company and  
Brunswick Southern Railway Company Limited

  
\_\_\_\_\_  
Ian Simpson  
General Manager

Montreal Maine & Atlantic Railway Limited

  
\_\_\_\_\_  
Robert Grindrod  
President

Sunbury Transport Limited



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Dale Thibodeau  
General Manager