Ottawa, March 16, 2015

Memorandum D8-2-19

Application of the *Investigation Drugs, Placebos and Emergency Drugs Remission Order*

In Brief

This document contains editing revisions that do not affect or change existing policies or procedures, including changes to the Canada Border Services Agency organizational structure.

This memorandum outlines the conditions under which a remission may be granted under the *Investigation Drugs, Placebos and Emergency Drugs Remission Order*.

Legislation

Investigation Drugs, Placebos and Emergency Drugs Remission Order, Sections 1 to 4

Guidelines and General Information

New Drugs for Emergency Treatment

1. Health Canada may issue a letter authorizing the sale of a quantity of a new drug for human or veterinary use to a practitioner named in the letter of authorization for use in the treatment of a patient under the care of that practitioner.

2. Such a letter of authorization shall state:

(a) the name of the practitioner to whom the new drug may be sold; and

(b) the quantity of the new drug that may be sold to that practitioner for that emergency.

3. A letter of authorization with the patient's name and the medical emergency information deleted is acceptable.

4. Exporters who ship emergency drugs to physicians in private practice or hospitals in Canada have been requested by Health Canada, to affix on all such shipments a label stating "Urgent — Emergency Drug."

Investigation Drugs and Placebos

5. Health Canada shall issue a letter of acknowledgment of a preclinical new drug submission (known as IND or investigational new drug submission) to the manufacturer of a new drug.

6. A manufacturer may sell a new drug to investigators qualified to use that drug, for the sole purpose of clinical testing to obtain evidence with respect to the safety, dosage and effectiveness of the new drug.

7. All inner and outer labels used in conjunction with the new drug so sold are to carry the statement "Investigation Drug" and "To be Used By Qualified Investigators Only".

Canada Border Services Agency (CBSA) Procedures

8. The goods imported under the provisions of this Order are to be accounted for on Form B3-3, *Canada Customs Coding Form* with special authority number 85-133 entered in field 26.

9. For the purposes of this Order, the references in section 4 to the Minister of National Revenue should be interpreted as Minister of Public Safety and Emergency Preparedness.

10. Investigation drugs and placebos imported under these Regulations must be accompanied by a letter of acknowledgment of a preclinical new drug submission issued by Health Canada.

11. Where the goods are imported under these Regulations and are not accompanied by a letter of acknowledgment for investigation drugs and placebos issued by Health Canada, or a letter of authorization for emergency drugs issued by e Health Canada, the importer must, within 90 days of the date of importation, present such documentation to the CBSA for inspection.

12. In cases where the drug named in the letter of acknowledgment or the covering letter is not identical to the drug named on the Form CI1, *Canada Customs Invoice*, a notarized statement from the importer is acceptable for CBSA purposes. Such a statement must include that both drug names do in fact represent the same drug.

13. A letter of acknowledgment with the drug's chemical structure deleted is acceptable for CBSA purposes.

14. Placebos imported subsequent to the importation of their corresponding investigation drug must be accompanied by the letter of acknowledgment for the investigation drug.

15. A single letter of authorization per accounting document is sufficient. Therefore, the quantity indicated in the letter of authorization need not equal the quantity imported.

16. If such documentation (i.e. letter of acknowledgment or letter of authorization) is not presented to the CBSA within the 90 day time limit, the CBSA will request an amendment of the accounting document on a Form B2, *Canada Customs –Adjustment Request* to account for the full duties and taxes on the goods.

17. For information relative to the importation of narcotics and controlled and restricted drugs, refer to Memorandum D19-9-2, *Importation and Exportation of Controlled Substances and Precursors*.

Additional Information

18. For more information, within Canada call the Border Information Service at **1-800-461-9999**. From outside Canada call 204-983-3500 or 506-636-5064. Long distance charges will apply. Agents are available Monday to Friday (08:00 – 16:00 local time / except holidays). TTY is also available within Canada: **1-866-335-3237**.

References	
Issuing Office	Trade and Anti-dumping Programs Directorate
Headquarters File	22001-1
Legislative References	*Financial Administration Act* *Customs Tariff* *Food and Drug Regulations*
Other References	D19-9-2 Forms B2, B3-3 and CI1
Superseded Memorandum D	D8-2-19 dated January 1, 1988