Health Canada Santé Canada

Therapeutic Products Directorate
Finance Building
101 Tunney's Pasture Driveway
Address Locator# 0202D2
Tunney's Pasture
OTTAWA, Ontario
K1A 0K9

9427-A1563-58

October 16, 2006 (signed)

[employee name removed]
Project Leader, Approval and
Compliance, Regulatory Affairs
sanofi-aventis Canada Inc.
2150 St. Elzear Boulevard West
LAVAL, Quebec
H7L 4A8

NOTICE OF COMPLIANCE WITH CONDITIONS-QUALIFYING NOTICE

[employee name removed]:

This Notice of Compliance with Conditions (NOC/c) Qualifying Notice, issued in accordance with the Health Canada NOC/c Policy, is to advise you that information submitted in support of the Supplemental New Drug Submission for **TAXOTERE (docetaxel)**, Control Number **093830**, for the indication of adjuvant treatment of patients with operable node-positive breast cancer, qualifies to be considered for authorization under the NOC/c Policy. In keeping with the provisions outlined in the NOC/c Policy, the following additional information is required to complete the assessment:

1. A letter, signed by the Chief Executive Officer or designated signing authority of sanofi-aventis Canada Inc, indicating that you agree to have this submission considered under the NOC/c Policy. Please be reminded that in agreeing to accept an NOC under the NOC/c Policy, sanofi-aventis Canada Inc consents to the posting of the NOC/c-QN on Health Canada's website.

2. A draft Letter of Undertaking signed by the Chief Executive Officer or designated signing authority of sanofi-aventis Canada Inc, having a form and content satisfactory to Health Canada, including commitments to supply the following:

Confirmatory Studies

I) A complete report of the protocol-specified final analysis of TAX 316, A multicenter phase III randomized trial comparing docetaxel in combination with doxorubicin and cyclophosphamide (TAC) versus 5-fluorouracil in combination *with doxorubicin and cyclophosphamide (FAC) as adjuvant treatment of operable breast cancer patients with positive axillary lymph nodes, [Information removed]*

Post Market Safety Monitoring Studies

Report of all serious ADRs that occurred in Canada and all serious unexpected ADRs that occurred outside of Canada should be forwarded within 15 days to the Marketed Health Products Directorate and the appropriate review bureau in Therapeutic Products Directorate in accordance with current regulations and guidelines.

Periodic Safety Update Reports (PSUR-Cs), to be submitted yearly to the Therapeutic Products Directorate, up to submission of final safety and efficacy data from the above named clinical study. PSURs should be prepared in accordance with International Conference on Harmonisation ICH Guidelines.

3. A draft of the “Dear Health Care Professional Letter” detailing the issuance of a Notice of Compliance under the NOC/c Policy for TAXOTERE for the indication of adjuvant treatment of patients with operable node-positive breast cancer.

4. A draft of the “Fact Sheet” outlining in lay language the potential risks, benefits and side effects of TAXOTERE for the indication of adjuvant treatment of patients with operable node-positive breast cancer.

5. A draft of the Product Monograph that is consistent with the requirements outlined in section 5.2.1 of the *Notice of Compliance with Conditions Guidance*. Please note that, if applicable, a boxed text must appear on the cover page, at the beginning of each major section of the Product Monograph (Parts I, II and III), the first page, and the start of the Consumer Information section, disclosing the nature of the authorization granted for TAXOTERE and the need to conduct confirmatory studies.

I wish to advise you that this Qualifying Notice is being issued in accordance with Health Canada's guidance and policy on the *Management of Drug Submissions* and *Notice of Compliance with Conditions*, respectively. Sponsors are instructed to submit a complete response (refer to "*Guidance for Industry; Notice of Compliance with Conditions*") to the outstanding information within **30** calendar days of the date of this letter.

In order to facilitate and to ensure proper processing, please include a revised Submission Certificate with your response, quote the product name and control number, and address all correspondence to Director, Submission and Information Policy Division, Director General's Office, Therapeutic Products Directorate, Finance Building, Tunney's Pasture, Address Locator 0201A1, Ottawa, Ontario, K1A 0K9.

Yours sincerely,

Original signed by

Barbara Rotter, Ph.D.
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