ANNEX B

Content of Recall Status Reports

Recall status reports required under Section VI, Subsection C.3. shall contain the following information at the minimum:

A. Name and number of establishments, date, and method of notification;

B. Name and number of establishments responding to the recall communication and quantity of health products on hand at the time it was received;

C. Name and number of establishments that did not respond (if needed, the identity of the non-responding consignees may be requested by the FDA);

D. Name and number of health products returned/accounted by each establishment communicated;

E. Results of effectiveness checks by MAH;

F. Estimated time of completion of the recall; and

G. How the health product is being quarantined;

In addition to the abovementioned information:

H. The initial status report shall contain details on the media announcement for Class I and II MAH – initiated recalls, Class III; and

I. The final status report shall contain:

1. Details on the final disposition of the recalled health products including destruction of warranted; and
2. Final inventory