Attachment B1 - Recommendation for Recall Classification and Termination

Note: Under RES, this information will be a continuation of the electronic recall record and many of these fields will be pre-populated as the recall recommendation data is inputted. However, the following fields need to be completed to justify termination.

1. **Product:** See Attachment B.

2. **Codes:** See Attachment B.

3. **Recalling Firm/Manufacturer:** See Attachment B.

4. **Reason for Recall Recommendation:** See Attachment B.

5. **Volume of Product in Commerce, Quantity Recovered, and Disposition:**

   Provide total volume of product distributed and under the recalling firm's control. Provide quantity of product recovered or corrected by the recalling firm. If no, or little product was found in the market, explain why (i.e., expired, short shelf life, rapid turnover, etc.). Indicate the recall was completed and provide verification of disposition or correction of recalled product.

6. **Distribution:** See Attachment B.

7. **Firm's Recall Strategy:**

   Describe the level of distribution to which the recall was extended. Provide complete description of the firm's recall notification and/or correction efforts. List the number of consignees responding to the firm's notification. Provide effectiveness checks accomplished and their findings, and/or other means the firm has to document the recall effectiveness. Provide district conclusion as to the adequacy of the firm's actions. If known, indicate steps the firm has taken to prevent similar occurrences.

8. **Violation:**

   Provide the section of law violated.

9. **Preventive Action:**

   Provide the action taken by the firm to prevent recurrence of the violation.

10. **District Audit Program:**

Describe actions taken by FDA (inspections, sample collections, etc.). Provide details of any publicity issued. Provide results of any FDA audit checks or auditing of records at the firm. List any legal action planned or underway.