Appendix A – Application Process for the Authorization of Reduced Risk Statements

1. The application shall be filed with the appropriate Food and Drug Administration (FDA) Center/Office.

2. The FDA shall acknowledge receipt of an application in writing within 3 days of its receipt. The acknowledgement shall state the date of receipt of the application.

3. The application shall include the following:

    a. the name and address of the manufacturer;
    b. the Product/s for which the Reduced Risk Statements is to be made and its particular characteristics;
    c. a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out with regard to the Reduced Risk Statements or, Reduced Risk Statements which are authorized, validated, accepted or permitted by reliable and mature national regulatory agencies, and any other material which is available to demonstrate that Reduced Risk Statements complies with the criteria provided for in this issuance;
    d. where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;
    e. a copy of other scientific studies which are relevant to that Reduced Risk Statements;
    f. a proposal for the wording of the Reduced Risk Statements for which authorization is sought including, as the case may be, specific conditions for use; and
    g. a summary of the application

4. In giving its opinion via the order, the FDA shall endeavor to respect a time limit of six (6) months from the date of receipt of a valid application. Such time limit shall be extended whenever the FDA seeks supplementary information from the applicant.

5. The FDA, where appropriate, request the applicant to supplement the particulars accompanying the application within a specified time limit. All applications shall be resolved within a non-extendible period of six (6) months.

6. In order to prepare its opinion, the FDA shall:

    a. verify that the proposed wording of the Reduced Risk Statements is substantiated by scientific data;
    b. consider whether the wording of the Reduced Risk Statements complies with the criteria laid down in this issuance;
    c. give advice on whether the proposed wording of the Reduced Risk Statements is understandable and meaningful to the average consumer.

7. In the event of an Order in favor of authorizing the Reduced Risk Statements, the opinion shall include the following particulars:

a. the name and address of the applicant;
b. the Product/s in respect of which a statement is to be made and its particular characteristics;
c. the recommended wording of the proposed Reduced Risk Statement; and
d. the accompanying health warning that the product is not risk-free.