(4) ANY SAMPLE OF THE DRUG AND OF ANY ARTICLE USED AS A COMPONENT OF THE DRUG THAT THE SECRETARY REQUIRES; AND

(5) A SPECIMEN OF THE LABELING THAT IS PROPOSED TO BE USED FOR THE DRUG.

(D) STANDARD FOR APPROVAL.

THE SECRETARY MAY NOT APPROVE AN APPLICATION FILED UNDER THIS SECTION UNLESS THE DRUG HAS BEEN TESTED AND, UNDER THE CONDITIONS SPECIFIED, RECOMMENDED, OR SUGGESTED IN THE PROPOSED LABELING OF THE DRUG, HAS BEEN FOUND TO BE SAFE FOR AND EFFECTIVE IN USE.

(E) AUTOMATIC APPROVAL OF APPLICATIONS; PROCEDURE AND GROUNDS FOR DISAPPROVAL.

AN APPLICATION FILED WITH THE SECRETARY UNDER THIS SECTION SHALL BE CONSIDERED APPROVED ON THE 180TH DAY AFTER IT IS FILED, UNLESS BEFORE THAT DAY AND AFTER GIVING THE APPLICANT NOTICE AND AN OPPORTUNITY FOR A HEARING, THE SECRETARY ISSUES AN ORDER OF DISAPPROVAL UNDER SUBSECTION (F) OF THIS SECTION ON A FINDING THAT:

(1) THE DRUG HAS NOT BEEN TESTED PROPERLY, AS REQUIRED BY SUBSECTION (D) OF THIS SECTION;

(2) UNDER THE CONDITIONS SPECIFIED, RECOMMENDED, OR SUGGESTED IN THE PROPOSED LABELING OF THE DRUG, IT IS NOT SAFE FOR OR EFFECTIVE IN USE;

(3) THE METHODS USED IN, AND THE FACILITIES AND CONTROLS USED FOR, THE MANUFACTURE, PROCESSING, AND PACKING OF THE DRUG ARE INADEQUATE TO PRESERVE ITS IDENTITY, STRENGTH, QUALITY, AND PURITY; OR

(4) BASED ON A FAIR EVALUATION OF ALL MATERIAL FACTS, THE PROPOSED LABELING IS FALSE OR MISLEADING IN ANY WAY.

(F) ORDER OF DISAPPROVAL.

IF, BEFORE THE DATE THAT THE APPLICATION OTHERWISE WOULD BE CONSIDERED APPROVED THE SECRETARY MAKES ANY OF THE FINDINGS THAT ARE ENUMERATED IN SUBSECTION (E) OF THIS SECTION CONCERNING THE DRUG, THE SECRETARY SHALL ISSUE AN ORDER THAT DISAPPROVES THE APPLICATION.

(G) REVOCATION OF DISAPPROVAL; REVOCATION OF APPROVAL.

(1) THE SECRETARY MAY REVOKE AN ORDER THAT DISAPPROVED AN APPLICATION AND THE APPLICATION THEN SHALL BE CONSIDERED APPROVED.