

(2) AFTER PROVIDING AN OPPORTUNITY FOR A PUBLIC HEARING AND JUDICIAL APPEAL, THE SECRETARY MAY REVOKE AN APPLICATION THAT WAS APPROVED UNDER THIS SECTION IF, BASED ON EVIDENCE THAT IS ACQUIRED AFTER APPROVAL, THE SECRETARY FINDS THAT:

(I) THE DRUG MAY NOT BE SAFE FOR OR EFFECTIVE IN ITS INTENDED USE; OR

(II) THE FACILITIES OR CONTROLS USED IN THE MANUFACTURE, PROCESSING, OR LABELING OF THE DRUG MAY PRESENT A HAZARD TO THE PUBLIC HEALTH.

(H) RECORDS AND REPORTS.

IN ACCORDANCE WITH ANY RULE OR REGULATION THAT IS ADOPTED OR ANY ORDER THAT IS ISSUED BY THE SECRETARY UNDER THIS SECTION, THE PERSON WHO HOLDS AN APPLICATION FOR A DRUG THAT IS APPROVED UNDER THIS SECTION SHALL:

(1) KEEP RECORDS; AND

(2) SUBMIT REPORTS TO THE SECRETARY.

(I) RULES, REGULATIONS, AND ORDERS ABOUT RECORDS AND REPORTS.

(1) THE SECRETARY MAY ADOPT RULES AND REGULATIONS THAT APPLY GENERALLY TO PERSONS WHOSE APPLICATIONS FOR DRUGS HAVE BEEN APPROVED OR, AS TO A PARTICULAR PERSON WHOSE APPLICATION HAS BEEN APPROVED, ISSUE AN ORDER THAT REQUIRES AN APPLICANT:

(I) TO KEEP RECORDS OF INFORMATION THAT RELATES TO CLINICAL EXPERIENCE WITH THE DRUG AND ANY OTHER INFORMATION THAT THE APPLICANT OBTAINS ABOUT THE DRUG; AND

(II) TO SUBMIT REPORTS TO THE SECRETARY CONCERNING THAT INFORMATION.

(2) WHEN ADOPTING A RULE OR REGULATION OR ISSUING AN ORDER THAT REQUIRES THE SUBMISSION OF INFORMATION UNDER THIS SUBSECTION, THE SECRETARY SHALL CONSIDER THE PROFESSIONAL ETHICS OF THE MEDICAL PROFESSION AND THE INTERESTS OF PATIENTS.

(3) ANY RULE, REGULATION, OR ORDER UNDER THIS SECTION SHALL PROVIDE THAT IF ANY PERSON TO WHOM THE RULE, REGULATION, OR ORDER APPLIES REQUESTS IT, AND IF THE SECRETARY CONSIDERS IT TO BE APPROPRIATE, THE PERSON MAY EXAMINE SIMILAR INFORMATION THAT IS OBTAINED BY THE SECRETARY CONCERNING THE DRUG.