ESTABLISH BY INFORMATION THAT IS SUBMITTED TO THE SECRETARY THAT THE RULE OR REGULATION IS NEEDED AND THAT THE EFFECT OF THE RULE OR REGULATION WILL NOT HARM THE PUBLIC HEALTH.

(3) IF THE INFORMATION SUBMITTED BY THE PETITIONER IS NOT SUFFICIENT TO ALLOW THE SECRETARY TO DETERMINE WHETHER, UNDER THE STANDARDS SET FORTH IN SUBSECTION (E) OF THIS SECTION, THE RULE OR REGULATION SHOULD BE ADOPTED, THE SECRETARY MAY REQUIRE THAT ADDITIONAL INFORMATION BE SUBMITTED. FAILURE BY THE PETITIONER TO COMPLY WITH THE SECRETARY'S REQUEST IS A SUFFICIENT GROUND TO DENY THE PETITION.

(E) FACTORS RELEVANT TO ADOPTING STATE RULES AND REGULATIONS.

THE SECRETARY, IN DETERMINING WHETHER TO ADOPT A RULE OR REGULATION UNDER THIS SECTION, SHALL CONSIDER:

(1) THE NAME OF AND ALL PERTINENT INFORMATION THAT CONCERNS THE SUBSTANCE OR ADDITIVE, INCLUDING, IF AVAILABLE:

(I) ITS CHEMICAL IDENTITY AND COMPOSITION;

(II) THE CONDITIONS OF ITS PROPOSED USE, INCLUDING DIRECTIONS, RECOMMENDATIONS, AND SUGGESTIONS;

(III) SAMPLES OF THE PROPOSED LABELING FOR THE SUBSTANCE OR ADDITIVE; AND

(IV) ALL RELEVANT INFORMATION BEARING ON THE PHYSICAL OR OTHER TECHNICAL EFFECT OF THE SUBSTANCE OR ADDITIVE AND THE QUANTITY OF THE SUBSTANCE OR ADDITIVE THAT IS REQUIRED TO PRODUCE THE EFFECT;

(2) THE PROBABLE COMPOSITION OF ANY SUBSTANCE THAT MAY BE FORMED IN OR ON A FOOD, DRUG, OR COSMETIC AS A RESULT OF THE USE OF THE SUBSTANCE OR ADDITIVE;

(3) THE PROBABLE AMOUNT OF THE SUBSTANCE OR ADDITIVE THAT WOULD BE CONSUMED IN THE AVERAGE HUMAN DIET, TAKING INTO ACCOUNT ANY CHEMICALLY OR PHARMACOLOGICALLY RELATED SUBSTANCE IN THE DIET;

(4) SAFETY FACTORS THAT, IN THE OPINION OF EXPERTS QUALIFIED BY SCIENTIFIC TRAINING AND EXPERIENCE TO EVALUATE THE SAFETY OF THE SUBSTANCE OR ADDITIVE FOR ITS PROPOSED USE, ARE GENERALLY RECOGNIZED AS APPROPRIATE FOR THE USE OF ANIMAL EXPERIMENTATION INFORMATION;

(5) THE AVAILABILITY OF A PRACTICABLE METHOD OF ANALYSIS FOR DETERMINING THE IDENTITY AND QUANTITY OF:

(I) THE SUBSTANCE OR THE ADDITIVE IN OR ON AN ARTICLE;