with these agents until the questions raised can be resolved. Limited human trials are continuing.

Our advisory committee has also agreed with our decision not to approve beta-blockers for use in angina because the evidence presently available in our files is inadequate to conclude that they are safe and effective for this use. Further studies are currently underway in this area.

One of the anti-hypertensive drugs mentioned by Dr. Freis has been under review by the agency and has not been approved because of the very poor quality of the data in the submission. In this instance we invited Dr. Freis in to review this data with us and he agreed that the deficiencies in the submission would have to be corrected with better data before approval should be considered.

These and other instances are examples of misinformation or incomplete information which sometimes is used to criticize the agency unjustly.

Senator NELSON. What controlled clinical studies were done in England or elsewhere in Europe that qualified it for the marketplace there?

Dr. EDWARDS. We don't know. We don't have that information. We have been in touch with experts in this field who are familiar with that data. Then, on the basis of their evaluation, they say it needs further trial, and they feel very uncomfortable with the general availability. There are side effects, and that should produce investigations at this time.

Senator NELSON. Do you have to prove efficacy to market a drug in England?

Dr. EDWARDS. I am not completely sure. It is changing now. I believe that their requirement is only for safety at the present time, but I am not certain.

Mr. GORDON. Have there been any previous occasions when committees have been established to attack FDA's regulations, which have been reported exclusively in the Medical Tribune?

Dr. EDWARDS. Many hundreds of lines have been printed on the UGDP study.

Senator NELSON. Which?

Dr. EDWARDS. The University Group Diabetic Program study.

Senator NELSON. The tolbutamide study?

Dr. EDWARDS. The tolbutamide study was done by the University Group. The Medical Tribune has been extremely critical of our position in this regard and we have received a petition. Mr. Hutt could speak better to that point.

Mr. HUTT. The petition was filed last year, October 7, 1971.

Senator NELSON. Petition filed by whom?

Mr. HUTT. By an attorney representing the Coordinating Committee of the Committee on the Care of the Diabetic, I believe is the name of it. It was submitted late last year and supplemented on January 10 of this year.

The request was for Food and Drug to withdraw its earlier announced policy with respect to proper and improper labeling of tolbutamide. The petition is still under consideration. The draft reply has been formulated and should be sent forward very soon. I would