will demonstrate that the product is bioavailable. To assist manufacturers who do not have the capability to determine dissolution by all three methods, the Food and Drug Administration is prepared, on request, to test samples of reformulated tablets by all three methods and to supply the results of these analyses to the manufacturer.

The references set forth in the preamble together with the following additional supportive data and background information have been assembled and are on display in the office of the Hearing Clerk, Food and Drug Administration, Room 6-86, 5600 Fishers Lane, Rockville, MD 20852: