**Variable Definitions for Online NME Approval Time Database**

counter2: just a stock (internal use) identifier for each drug

Revisedgenernam – NME's generic name

Revisedtrname – NME's trade name, if any

Revisedndanum1 – unique FDA-given identifier for drug application of NME

Revisedfirm – firm sponsoring NME

Revisedfirmcode – unique numeric identifier for firm sponsoring NME

indic1 – primary indication disease of NME

reviseddiscode – unique identifier for primary indication disease of NME

PriorityReview – dummy for priority review

StandardReview – dummy for non-priority review

Revisedsubyear – year of NME submission

Revisedsubdate – date of NME submission

Revisedappdate – date of approval

Revisedappyear – year of approval

Revisedapptime – time to approval, in months

Uniquenmeorderent – order of entry into primary indication niche market (= number of previously approved NMEs for this primary indication, plus one)

Uniquenmefirst – dummy for whether NME is first in primary indication niche

UniqueNMEFirmSub – number of NMEs previous submitted by firm sponsoring present NME

Uniquenmefirmapp – number of NMEs previously submitted and accepted by firm sponsoring present NME

Lnrevisedapptime – approval time in months (logged)

Lnuniquenmeorderent – order of entry (logged)

dum1962 – dummy for if drug was submitted after passage of Kefauver-Harris Amendments

dizcode – previous version of primary indication code

stffcder – staff of drug-reviewing division or bureau in year when NME was submitted