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