Attachment B

DRUG FORMULARY COMMISSION

Required Data and Optional Information to be Submitted with Petitions for Multivitamin Prescription Products

ORDER	CRITERION	REQUIREMENT
A	Name of reference drug	y
B	Federal regulatory status (B coded, pre-38, DESI)	y
C	FDA observational inspection (Form 482) for manufacturer	y
D	FDA inspection report for laboratory performing certifications (assays or analysis)	y
E	Special FDA requirements if any	y (if applicable)
F	Meets USP standards	y
G	List of the vitamins and minerals in the product	y
H	Dose of each vitamin and mineral in the products	y
I	Assay of active ingredients for petitioner and reference products	y
J	Comparison of dissolution profiles - Certificate of analysis	y
K	Data on clinical and therapeutic comparability	y (if narrow therapeutic index[1] and bioequivalence not essential[2])
L	Significant new information	y (if petition previously voted upon)
M	Formularies of other states or hospitals	optional
N	Other supporting information	optional

[1] Requires careful patient titration and monitoring for safe and effective use.
[2] As determined by the Drug Formulary Commission.