GUIDANCE FOR
DETERMINING WHETHER A PHARMACY IS AUTHORIZED TO COMPOUND AND/OR
MANUFACTURE DRUGS IN NEW YORK STATE

Recent events have focused much attention in both the professional and public press on the
distinction between the practice of compounding and the manufacture of drugs in New York State.
We offer this guidance to assist institutions and private practices as they seek sources of essential
medications.

Pharmacies registered to operate in New York State, whether physically located within the State or
located in other states and registered as non-resident pharmacies, are all subject to the same
practice requirements in New York. New York State does not formally register or distinguish
“specialty” pharmacies, such as “compounding pharmacies.”

Within the context of New York State’s laws and regulations, all pharmacists, presuming they are
competent to do so, may engage in compounding. However, compounding and dispensing by
pharmacists and pharmacies is limited to patient-specific prescriptions or orders. New York does
not permit compounding “for physician’s office use” because it involves the dispensing of non-
patient specific orders. Instead, New York considers this type of activity to be “manufacturing”.

Some confusion exists over the term “registered manufacturer” as used by the federal government.
In fact, all firms wishing to engage in manufacturing must register with the federal Food and Drug
Administration (FDA) and be listed as a manufacturer on the FDA’s web site. However, such
entities must also obtain FDA approval for each drug it seeks to manufacture. To determine which
drugs are expressly approved by the FDA for a particular manufacturer, you should refer to the
electronic version of the Orange Book, which is updated daily and is available on the FDA website at:

http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm

In addition even if an establishment is considered a “registered manufacturer” with the federal
government (FDA), in order to manufacture drugs in New York State, the establishment must be
registered with the New York State Education Department, through its Board of Pharmacy.
Confirmation of appropriate New York State Registration is available at:

http://www.op.nysed.gov/opsearches.htm

We hope this information is helpful. Additional questions and may be directed to us at our email
address at: Pharmbd@mail.nysed.gov