under the investigational use provi-
sions of part 312 of this chapter, but
does not include internal or interplant
transfer of a bulk product substance
between registered establishments
within the same parent, subsidiary,
and/or affiliate company. For foreign
establishments, the term “commercial
distribution” shall have the same
meaning except that the term shall not
include distribution of any blood or
blood product that is neither imported
nor offered for import into the United
States.

(f) Any material change includes but is
not limited to any change in the name
of the blood product, in the quantity or
identity of the active ingredient(s) or
in the quantity or identity of the inac-
tive ingredient(s) where quantitative
listing of all ingredients is required
pursuant to §607.31(a)(2) and any sig-
nificant change in the labeling of a
blood product. Changes that are not
significant include changes in arrange-
ment or printing or changes of an edi-
torial nature.

(g) Bulk product substance means any
substance that is represented for use in
a blood product and when used in the
manufacturing of a blood product be-
comes an active ingredient or a fin-
ished dosage form of such product.

(h) Advertising and labeling include
the promotional material described in
§202.1(l) (1) and (2) of this chapter,
respectively.

(i) The definitions and interpreta-
tions contained in sections 201 and 510
of the act shall be applicable to such
terms when used in this part 607.

(j) United States agent means a person
residing or maintaining a place of busi-
ness in the United States whom a for-
eign establishment designates as its
agent. This definition excludes mail-
boxes, answering machines or services,
or other places where an individual
acting as the foreign establishment’s
agent is not physically present.

[40 FR 52788, Nov. 12, 1975, as amended at 55
FR 11014, Mar. 26, 1990; 66 FR 59158, Nov. 27,
2001]