processes. In such instances a written record of the program shall be main-
tained along with appropriate valida-
tion data. Hard copy or alternative sys-
tems, such as duplicates, tapes, or
microfilm, designed to assure that
backup data are exact and complete
and that it is secure from alteration,
 inadvertent erasures, or loss shall be
maintained.
(c) Such automated equipment used
for performance of operations ad-
dressed by §§211.101(c) or (d), 211.103,
211.182, or 211.188(b)(11) can satisfy the
requirements included in those sec-
tions relating to the performance of an
operation by one person and checking
by another person if such equipment is
used in conformity with this section,
and one person checks that the equip-
ment properly performed the oper-
ation.
[43 FR 45077, Sept. 29, 1978, as amended at 60
FR 4091, Jan. 20, 1995; 73 FR 51932, Sept. 8,
2008]
§ 211.72 Filters.
Filters for liquid filtration used in
the manufacture, processing, or pack-
ing of injectable drug products in-
tended for human use shall not release
fibers into such products. Fiber-releas-
ing filters may be used when it is not
possible to manufacture such products
without the use of these filters. If use
of a fiber-releasing filter is necessary,
an additional nonfiber-releasing filter
having a maximum nominal pore size
rating of 0.2 micron (0.45 micron if the
manufacturing conditions so dictate)
shall subsequently be used to reduce
the content of particles in the
injectable drug product. The use of an
asbestos-containing filter is prohibited.
[73 FR 51932, Sept. 8, 2008]
Subpart E—Control of Compo-
nents and Drug Product Con-
tainers and Closures
§ 211.80 General requirements.
(a) There shall be written procedures
describing in sufficient detail the re-
cipient, identification, storage, handling,
sampling, testing, and approval or re-
jection of components and drug prod-
uct containers and closures; such writ-
ten procedures shall be followed.
(b) Components and drug product
containers and closures shall at all
times be handled and stored in a man-
ner to prevent contamination.
(c) Bagged or boxed components of
drug product containers, or closures
shall be stored off the floor and suit-
ably spaced to permit cleaning and in-
spection.
(d) Each container or grouping of
containers for components or drug
product containers, or closures shall be
identified with a distinctive code for
each lot in each shipment received.
This code shall be used in recording the
disposition of each lot. Each lot shall be
appropriately identified as to its
status (i.e., quarantined, approved, or
rejected).
§ 211.82 Receipt and storage of untest-
ed components, drug product con-
tainers, and closures.
(a) Upon receipt and before accept-
ance, each container or grouping of
containers of components, drug prod-
uct containers, and closures shall be
examined visually for appropriate la-
beling as to contents, container dam-
age or broken seals, and contamina-
tion.
(b) Components, drug product con-
tainers, and closures shall be stored
under quarantine until they have been
tested or examined, whichever is appro-
priate, and released. Storage within
the area shall conform to the require-
ments of §211.80.
[43 FR 45077, Sept. 29, 1978, as amended at 73
FR 51932, Sept. 8, 2008]
§ 211.84 Testing and approval or rejec-
tion of components, drug product con-
tainers, and closures.
(a) Each lot of components, drug
product containers, and closures shall be
withheld from use until the lot has
been sampled, tested, or examined, as
appropriate, and released for use by the
quality control unit.
(b) Representative samples of each
shipment of each lot shall be collected
for testing or examination. The num-
ber of containers to be sampled, and
the amount of material to be taken
from each container, shall be based
upon appropriate criteria such as sta-
tistical criteria for component varia-
ability, confidence levels, and degree of