(b) Research begun on or after effective
date. FDA will accept studies sub-
mitted in support of a PMA which have
been conducted outside the United
States and begun on or after November
19, 1986, if the data are valid and the in-
vestigator has conducted the studies in
conformance with the “Declaration of
Helsinki” or the laws and regulations
of the country in which the research is
conducted, whichever accords greater
protection to the human subjects. If
the standards of the country are used,
the applicant shall state in detail any
differences between those standards
and the “Declaration of Helsinki” and
explain why they offer greater protec-
tion to the human subjects.

(c) Research begun before effective
date. FDA will accept studies sub-
mitted in support of a PMA which have
been conducted outside the United
States and begun before November 19,
1986, if FDA is satisfied that the data
are scientifically valid and that the
rights, safety, and welfare of human
subjects have not been violated.

(d) As sole basis for marketing approval.
A PMA based solely on foreign clinical
data and otherwise meeting the cri-
teria for approval under this part may
be approved if:
(1) The foreign data are applicable to
the U.S. population and U.S. medical
practice;
(2) The studies have been performed
by clinical investigators of recognized
competence; and
(3) The data may be considered valid
without the need for an on-site inspec-
tion by FDA or, if FDA considers such
an inspection to be necessary, FDA can
validate the data through an on-site in-
spection or other appropriate means.

(e) Consultation between FDA and ap-
plicants. Applicants are encouraged to
meet with FDA officials in a “pre-
submission” meeting when approval
based solely on foreign data will be
sought.

(Approved by the Office of Management and
Budget under control number 0910–0231)
[51 FR 26364, July 22, 1986; 51 FR 40415, Nov.
7, 1986, as amended at 51 FR 43344, Dec. 2,
1986]

§ 814.17 Service of orders.

Orders issued under this part will be
served in person by a designated officer
or employee of FDA on, or by reg-
istered mail to, the applicant or the
designated agent at the applicant’s or
designated agent’s last known address
in FDA’s records.

§ 814.19 Product development protocol
(PDP).

A class III device for which a product
development protocol has been de-
clared completed by FDA under this
chapter will be considered to have an
approved PMA.

Subpart B—Premarket Approval
Application (PMA)

§ 814.20 Application.

(a) The applicant or an authorized
representative shall sign the PMA. If
the applicant does not reside or have a
place of business within the United
States, the PMA shall be countersigned
by an authorized representative resid-
ing or maintaining a place of business
in the United States and shall identify
the representative’s name and address.

(b) Unless the applicant justifies an
omission in accordance with paragraph
(d) of this section, a PMA shall include:
(1) The name and address of the ap-
plicant.
(2) A table of contents that specifies
the volume and page number for each
item referred to in the table. A PMA
shall include separate sections on non-
clinical laboratory studies and on clin-
ical investigations involving human
subjects. A PMA shall be submitted in
six copies each bound in one or more
numbered volumes of reasonable size.
The applicant shall include informa-
tion that it believes to be trade secret
or confidential commercial or financial
information in all copies of the PMA
and identify in at least one copy the in-
formation that it believes to be trade
secret or confidential commercial or fi-
nancial information.

(3) A summary in sufficient detail
that the reader may gain a general un-
derstanding of the data and informa-
tion in the application. The summary
shall contain the following informa-
tion:
(i) Indications for use. A general de-
scription of the disease or condition
the device will diagnose, treat, prevent,