§ 1702.4
by this part, or a satisfactory expla-
nation for the absence of the informa-
tion. As provided by §1702.4, a petition
which is not complete may be closed.
To be considered complete, a petition
shall include the following:

(1) A statement of the justification
for the exemption in accordance with
§1702.7.

(2) All reasonably available human
experience data, reasonably available
relevant experimental data (both
human and animal), product and pack-
inging specifications, labeling, and mar-
keting history, in accordance with
§§1702.8 through 1702.14.

(b) As used in this regulation, “rea-
sonably available” information is data
in the petitioner’s possession; data
that has previously been generated by
the petitioner, and data that is obtain-
able from such sources as: Reports
from Poison Control Centers; reports of
adverse reactions that have been sub-
mitted to the petitioner; the medical,
pharmacological, and toxicological lit-
erature; and information required by
the FDA for an Investigational Exemp-
tion for a New Drug (IND) or a New
Drug Application (NDA).

§ 1702.4 Petitions with insufficient or
incomplete information.

If a petition is submitted that is not
complete and does not explain the rea-
son for the absence of the information,
the Commission shall afford the peti-
tioner a reasonable opportunity to pro-
vide additional information. If the re-
quired information is not submitted to
the Commission, or if the petitioner
does not satisfactorily explain the ab-
sen ce of the information within a rea-
sonable time, the petition shall be
closed if insufficient or incomplete in-
formation has been submitted to en-
able the Commission to evaluate the
merits of the exemption request.

§ 1702.5 Failure to supply adverse in-
formation.

Failure to obtain and provide the
Commission with all reasonably avail-
able information that the petitioner
knows is unfavorable or could reason-
ably expect to be unfavorable to the pe-
tition shall result in the denial of the
petition.

§ 1702.6 Trade secrets and other con-
fidential information.

Where a petition contains material
that the petitioner believes should be
exempt from public disclosure under
the Freedom of Information Act, 5
U.S.C. 552, the petitioner shall comply
with the requirements of 16 CFR part
1015. the Commission’s regulation
under the Freedom of Information Act
concerning requests for treatment as
exempt material. The Commission
shall act upon any request for treat-
ment as exempt material in accordance
with the provisions of 16 CFR part 1015.

§ 1702.7 Justification for the exemp-
tion.

The justification for the exemption,
required under §1702.3, shall explain
the reason for the exemption based on
one or more of the following grounds:

(a) If the justification is based on a
lack of need for special packaging to
protect young children from serious in-
jury or illness from the substance, the
justification shall state how the lack of
toxicity and lack of adverse human ex-
perience for the substance clearly sup-
ports granting the exemption.

(b) If the exemption is requested be-
cause special packaging is not techno-
logically feasible, practicable, or ap-
propriate for the substance, the jus-
tification shall explain why.

(c) If the exemption is requested be-
cause special packaging is incompat-
ible with the particular substance, the
justification shall explain why.

§ 1702.8 Human experience data.

Human experience data constitutes
the primary criterion used by the Com-
mission in evaluating petitions for ex-
emptions. Petitions shall therefore in-
clude a compilation of all reasonably
available reports pertaining to human
use of the particular substance, includ-
ing the product brand as well as ge-
neric equivalents and involving adverse
reports of personal injury, illness, and
significant allergenicity. Such infor-
mation in children is of particular im-
portance in evaluating exemption re-
quests. However, similar data in adults
shall also be submitted if available.
Human experience data may be ob-
tained from such sources as: