by this part, or a satisfactory explanation for the absence of the information. 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 packaging specifications, labeling, and marketing history, in accordance with §§1702.8 through 1702.14,

(b) As used in this regulation, "reasonably available" information is data in the petitioner's possession; data that has previously been generated by the petitioner, and data that is obtainable from such sources as: Reports from Poison Control Centers; reports of adverse reactions that have been submitted to the petitioner; the medical, pharmacological, and toxicological literature; and information required by the FDA for an Investigational Exemption 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 reason for the absence of the information, the Commission shall afford the petitioner a reasonable opportunity to provide additional information. If the required information is not submitted to the Commission, or if the petitioner does not satisfactorily explain the absence of the information within a reasonable time, the petition shall be closed if insufficient or incomplete information has been submitted to enable the Commission to evaluate the merits of the exemption request.

§1702.5 Failure to supply adverse information.

Failure to obtain and provide the Commission with all reasonably available information that the petitioner knows is unfavorable or could reasonably expect to be unfavorable to the petition shall result in the denial of the petition.

§1702.6 Trade secrets and other confidential 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 treatment as exempt material in accordance with the provisions of 16 CFR part 1015.

§1702.7 Justification for the exemption.

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 injury or illness from the substance, the justification shall state how the lack of toxicity and lack of adverse human experience for the substance clearly supports granting the exemption.

(b) If the exemption is requested because special packaging is not technologically feasible, practicable, or appropriate for the substance, the justification shall explain why.

(c) If the exemption is requested because special packaging is incompatible with the particular substance, the justification shall explain why.

§1702.8 Human experience data.

Human experience data constitutes the primary criterion used by the Commission in evaluating petitions for exemptions. Petitions shall therefore include a compilation of all reasonably available reports pertaining to human use of the particular substance, including the product brand as well as generic equivalents and involving adverse reports of personal injury, illness, and significant allergenicity. Such information in children is of particular importance in evaluating exemption requests. However, similar data in adults shall also be submitted if available. Human experience data may be obtained from such sources as:

(a) Reports from Poison Control Centers,

(b) Reports of adverse reactions relative to the product that have been submitted to the company by physicians, hospitals, consumers, and other sources,

(c) Extensive searches of the medical, pharmacological, and toxicological literature, and

(d) For drugs, where the human experience data submitted is based on data required by FDA to be compiled for an Investigational Exemption for a New Drug (IND), 21 CFR part 312, or a New Drug Application (NDA), 21 CFR part 314, a summary of the relevant data should be provided. The entire NDA and IND material need not be submitted.

§ 1702.9 Relevant experimental data.

Experimental data are generated in both animals and humans in controlled situations in order to evaluate the biological effects of a substance. Certain toxicological effects cannot generally be evaluated in human beings. This is especially true of those substances which are not normally intended to be used in or on the human body or animal body. Therefore, the Commission considers experimental data obtained in animal studies to be an important supplement to such data as may exist from any experimental studies conducted in humans. The minimum toxicological evaluation necessary for a particular household substance is proportional to the expected exposure of man to that substance. Household substances which are not expected, in normal use, to contact man are subject to less extensive studies than those substances, such as drugs, which are designed to be used in or on man. The Commission has, therefore, separated the requirements of this section into three subsections. Section 1702.9(a) lists minimum acute animal toxicity data which shall be submitted, if reasonably available, for all petitions; §1702.9(b) lists those additional data which shall be submitted, if reasonably available, for drug products and all other household substances which are normally intended to be used in or on the human body; and §1702.9(c) lists those additional data which shall be submitted, if reasonably available, by petitioners requesting exemption for substances not intended for use in or on the human or animal body. The Commission emphasizes that, while not absolutely necessary, the types of data outlined in §1702.9(c) may greatly expedite the Commission's evaluation of a particular exemption request.

(a) *General criteria applicable to all petitions.* (1) Each petition for an exemption under this part shall include all reasonably available relevant experimental data relating to the petition regardless of whether such data are unfavorable to the petitioner's request. As used in this part, the term "relevant experimental data" includes, but is not limited to, all data, including animal and human studies revealing the nature and degree of the hazard associated with the particular substance. Generally, the hazard associated with the particular substance involves the risk of injury arising from the acute accidental ingestion of a product. Where a hazard different from the risk of injury arising from accidental ingestion is known to exist (e.g., potential for significant allergenicity, dermal or opthalmic injury from handling or using the product), the petitioner shall also submit all reasonably available relevant experimental data evaluating the nature and degree of any additional hazard(s).

(2) All animal studies submitted in support of exemption requests should be performed in conformity with good pharmacological and toxicological practice which includes, as a minimum, complete descriptions of protocols used in experimental animal studies, and signed laboratory reports which include the following basic information:

(i) An exact description of materials tested;

(ii) A description of test animals employed in studies, including number, age, weight, sex and nutritional state of animals;

(iii) Dosage level(s) and number of animals tested per dosage level;

(iv) Basis upon which dosage was administered (e.g., as salt or base);

(v) Route of administration and dosage volume; and