limited, listing of all items in the recommended order would preempt those labeling statements required by law. The second comment also requested that the general warning statements, ''Keep this and all drugs out of the reach of children'' and ''In case of accidental ingestion call a Poison Control Center, emergency medical facility, or a doctor,'' not be included in the Panel's priority system of labeling. The comment pointed out that warnings similar to these are already required by 21 CFR 330.1(g), which only requires that these warnings appear somewhere in the labeling. The comment stated that there is no basis for special treatment of these warnings for OTC vaginal contraceptive drug products.

Existing regulations (21 CFR 201.15 and 21 CFR part 201, subpart C—Labeling Requirements for Over–the–Counter Drugs) adequately address the placement and prominence of labeling statements. While there may be certain selected situations where it is necessary to alter these general requirements, the agency is unaware of any data demonstrating that it is necessary in the case of OTC vaginal contraceptive drug products. In addition, the labeling statements required by § 330.1(g) are similar to those recommended by the Panel and the agency considers the labeling requirements in § 330.1(g) to be appropriate for OTC vaginal contraceptive drug products.

14. One comment suggested that the accidental ingestion warning recommended by the Panel be changed from ''In case of accidental ingestion, call a Poison Control Center, emergency medical facility, or a doctor immediately'' to ''In case of accidental ingestion of large amounts by children, call a Poison Control Center or emergency medical facility, or call a doctor.'' The comment contended that because of the well-established safety of OTC vaginal contraceptive drug products the Panel's recommended warning is unnecessarily alarming to adult users.

The agency does not believe that the Panel or the comment have presented sufficient data or information to warrant a change from the accidental ingestion warning required by § 330.1(g) or § 369.9 for all OTC drug products.

15. One comment agreed with the Panel that the labeling of an OTC contraceptive drug product should contain an expiration date and information on the product's appropriate storage condition.

To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, existing FDA regulations at 21 CFR 211.137 require an expiration date for the product, except for OTC drug products for human use whose labeling does not bear dosage limitations and which are stable for at least 3 years as supported by appropriate stability data. In addition, the expiration date is also required to relate to any storage conditions stated on the labeling. As discussed in section I.A., comment 3 of this document, the agency is proposing that each OTC vaginal contraceptive drug product should be the subject of an approved application prior to marketing. Information relating to dosage limitations, stability conditions, and storage conditions should be included in the application.

16. Three comments agreed with the Panel that the labeling of OTC vaginal contraceptive drug products should contain precise directions that can be easily understood by the average consumer. One of these comments added that diagrams on proper use of the contraceptive might also be useful.

The agency agrees that vaginal contraceptives should contain precise directions that are understandable to consumers, including diagrammed instructions, as appropriate, to show the proper method of application.

17. One comment suggested that the Panel's recommended directions statement in § 351.56(a)(3), which reads, ''If this product is used together with another contraceptive method, there will probably be better protection against pregnancy,'' be modified to include examples of various contraceptive methods, such as a diaphragm, condom, or intrauterine device.

As discussed in section I. C., comment 12 of this document, the agency believes that the labeling of OTC vaginal contraceptive drug products should contain a summary of the effectiveness of the various methods of contraception. In light of this, the agency considers the modification recommended by the comment to be unnecessary.

18. One comment stated that if the indication recommended by the Panel in § 351.56(b)(5), which reads, ''Extra protection for women who forget to take one or more contraceptive pills,'' is adopted, the labeling of the product should also refer the user to the directions for use of the oral contraceptive. The comment reasoned that a woman who has missed more than two consecutive pills should discontinue taking them, whereas the use of the word ''extra'' implies that the pills should be continued. As an alternative to referring the user to the oral contraceptive's directions for use, the comment suggested revising the statement to read ''Extra protection for women who forget to take one or two contraceptive pills.''

The comment added that the indication in recommended § 351.56(b)(8), which reads, ''Effective contraceptive alone or in the event the contraceptive pill is forgotten,'' is more acceptable than the one in § 351.56(b)(5), but it appears to imply that vaginal and oral contraceptives provide equivalent protection. The comment recommended that both statements either be modified or deleted.

The agency believes that information regarding what to do when a contraceptive pill is forgotten is more appropriate for inclusion in the labeling of oral contraceptives. Such information is required to be included in the patient labeling of oral contraceptives. Therefore, the agency does not believe that this type of information is necessary for inclusion in the labeling for OTC vaginal contraceptive drug products.

19. Two comments urged deletion of the statement recommended by the Panel in § 351.56(a)(5), which reads, ''If douching is desired, always wait at least 6 hours after intercourse before douching.'' The comments claimed that there are no data or information in the scientific literature or from common usage demonstrating the need for such labeling. One of these comments specifically argued that the only supporting reference cited by the Panel (Ref. 1) discusses the persistence of sperm in the cervix and vagina following intercourse but does not express any concern about douching following the use of a vaginal spermicide. The comment added that this reference actually indicates that douching was ''associated with reductions in proportions of smears containing spermatozoa.'' Both comments also specifically noted that the Panel admitted that there are no data establishing the optimum time interval between use of a spermicide and douching.

Although the comments are correct that no data are available concerning the optimum time interval between intercourse and douching when using a vaginal spermicide product, it is generally accepted that douching too soon after intercourse could likely interfere with a spermicide by diluting it or removing it from the vagina. Therefore, the agency believes that a statement regarding the time interval between intercourse and douching would provide useful information to the consumer. The Panel stated that it is