aid professional, user, or prospective user who requests a copy in writing.

(d) *Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a)(1) of this section or any written statement waiving medical evaluation required under paragraph (a)(2)(iii) of this section.

(e) *Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

[42 FR 9296, Feb. 15, 1977]

§ 801.425 Nonrestricted devices in self-pressurized containers with chlorofluorocarbon propellants.

(a) The label on each package of a nonrestricted device in a self-pressurized container in which the propellant consists in whole or in part of a fully halogenated chlorofluoroalkane (chlorofluorocarbon) shall bear the following warning:

Warning—Contain a chlorofluorocarbon that may harm the public health and environment by reducing ozone in the upper atmosphere.

(b) The warning required by paragraph (a) of this section shall appear on an appropriate panel with such prominence and conspicuousness as to render it likely to be read and understood by ordinary individuals under normal conditions of purchase. The warning may appear on a firmly affixed tag, tape, card, sticker or similar overlabeling attached to the package. The warning shall appear prominent and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background, but in no case may the letter be less than 1/16 inch in height.

(c) The warning in paragraph (a) of this section is not required and should not be used for products intended for metered-dose adrenergic bronchodilators for oral inhalation, and for cytology fixative uses.

(d) The warning required by paragraph (a) of this section is applicable only to self-pressurized containers that use a chlorofluorocarbon in whole or in part as a propellant to expel from the container liquid or solid material different from the propellant.

[42 FR 22034, Apr. 29, 1977]

§ 801.427 Professional and patient labeling for intrauterine contraceptive devices.

(a) This section applies to intrauterine devices (IUD's) that are not subject to new drug requirements under § 310.502 of this chapter. IUD's subject to this section (device IUD's) include:

(1) IUD's fabricated solely from inactive materials, e.g., inactive plastics or metals.

(2) IUD's with substances added to improve the physical characteristics if such substances do not contribute to contraception through chemical action on or within the body and are not dependent upon being metabolized for the achievement of the contraceptive purpose.

(3) IUD's that contain a component, such as barium, added exclusively for the purpose of visualization by x-ray.

(b) The intrauterine contraceptive device (IUD) is a popular method of contraception used by several million women in the United States. Although this method of contraception is generally safe and effective, certain complications and side effects may result from its use. A Food and Drug Administration review of the labeling of IUD's currently marketed in the United States reveals that information necessary for the safe and effective use of these products is not uniformly available to either the practitioner or the patient. Based on the review of the labeling and on the recommendations of the Ad Hoc Obstetric-Gynecology Advisory Committee, the Commissioner has concluded that in the interest of safe and effective use, and prevention of misleading labeling, there is a need to establish uniform physician and patient labeling for such devices.

(1) Labeling accompanying each IUD and directed to the physician shall be substantially as follows adjusted where appropriate to the requirements of a particular device IUD:

DESCRIPTION

(TO BE SUPPLIED BY MANUFACTURER)

Description shall include the following information:

1. Proprietary or established name of the IUD.
2. Major ingredients or composition.
3. Model.
4. Physical dimensions (size and shape).
5. Description of components in package or system.
6. A statement that the product is sterile.
7. Other characteristics.

MODE OF ACTION OR PRINCIPLES OF IUD DESIGN

(TO BE SUPPLIED BY THE MANUFACTURER)

The manufacturer shall include information on the mode of action or principles of the IUD's design. At a minimum, the statement should provide that IUD's seem to interfere in some manner with nidation in the endometrium, probably through foreign body reaction in the uterus.

INDICATIONS AND USAGE

The labeling may include indications and usages other than those stated below, provided that an approved premarket approval application is in effect. (Name of IUD) is indicated for contraception.

CONTRAINDICATIONS

IUD's should not be inserted when the following conditions exist:

1. Pregnancy or suspicion of pregnancy.
2. Abnormalities of the uterus resulting in distortion of the uterine cavity.
3. Acute pelvic inflammatory disease or a history of repeated pelvic inflammatory disease.
4. Post partum endometritis or infected abortion in the past 3 months.
5. Known or suspected uterine or cervical malignancy including unresolved, abnormal ''Pap'' smear.
6. Genital bleeding of unknown etiology.
7. Untreated acute cervicitis until infection is controlled.

WARNINGS

1. *Pregnancy*—a. *Long-term effects.* Long-term effects on the offspring when pregnancy occurs with (name of IUD) in place are unknown.

b. *Septic abortion.* Reports have indicated an increased incidence of septic abortion associated in some instances with septicemia, septic shock, and death in patients becoming pregnant with an IUD in place. Most of these reports have been associated with the midtrimester of pregnancy. In some cases, the initial symptoms have been insidious and not easily recognized. If pregnancy should occur with an IUD in place, the IUD should be removed if the string is visible or, if removal proves to be or would be difficult, termination of the pregnancy should be considered and offered the patient as an option bearing in mind that the risks associated with an elective abortion increase with gestational age.

c. *Continuation of pregnancy.* If the patient chooses to continue the pregnancy, she must be warned of the increased risk of spontaneous abortion and of the increased risk of sepsis, including death if the pregnancy continues with the IUD in place. The patient must be closely observed and she must be advised to report all abnormal symptoms, such as flu-like syndrome, fever, abdominal cramping and pain, bleeding, or vaginal discharge, immediately because generalized symptoms of septicemia may be insidious.

2. *Ectopic pregnancy.* a. A pregnancy that occurs with an IUD in place is more likely to be ectopic than a pregnancy occurring without an IUD in place. Accordingly, patients who become pregnant while using the IUD should be carefully evaluated for the possibility of an ectopic pregnancy.

b. Special attention should be directed to patients with delayed menses, slight metrorrhagia and/or unilateral pelvic pain and to those patients who wish to terminate a pregnancy because of IUD failure to determine whether ectopic pregnancy has occurred.

3. *Pelvic infection.* Pelvic infection may occur with the IUD in place and at times result in the development of tubo-ovarian abscesses or general peritonitis. Appropriate aerobic and anaerobic bacteriological studies should be done and antibiotic therapy initiated. If the infection does not show a marked clinical improvement within 24 to 48 hours, the IUD should be removed and the continuing treatment reassessed based upon the results of culture and sensitivity tests.

4. *Embedment.* Partial penetration or lodging of the IUD in the endometrium can result in difficult removals.

5. *Perforation.* Partial or total perforation of the uterine wall or cervix may occur with the use of IUD's. The possibility of performation must be kept in mind during insertion and at the time of any subsequent examination. If perforation occurs, the IUD should be removed. Adhesions, foreign body reactions, and intestinal obstruction may result if an IUD is left in the peritoneal cavity.

PRECAUTIONS

1. *Patient counseling.* Prior to insertion the physician, nurse, or other trained health professional must provide the patient with the Patient Brochure. The patient should be given the opportunity to read the brochure and discuss fully any questions she may have concerning the IUD as well as other methods of contraception.

2. *Patient evaluation and clinical considerations.* a. A complete medical history should be obtained to determine conditions that might influence the selection of an IUD. Physical examination should include a pelvic examination, ''Pap'' smear, gonorrhea culture and, if indicated, appropriate tests for other forms of venereal disease.

b. The uterus should be carefully sounded prior to insertion to determine the degree of patency of the endocervical canal and the internal os, and the direction and depth of the uterine cavity. In occasional cases, severe cervical stenosis may be encountered. Do not use excessive force to overcome this resistance.

c. The uterus should sound to a depth of 6 to 8 centimeters (cm). Insertion of an IUD into a uterine cavity measuring less than 6.5 cm by sounding may increase the incidence of expulsion, bleeding, and pain.

d. The possibility of insertion in the presence of an existing undetermined pregnancy is reduced if insertion is performed during or shortly following a menstrual period. The IUD should not be inserted post partum or postabortion until involution of the uterus is completed. The incidence of perforation and expulsion is greater if involution is not completed.

e. IUD's should be used with caution in those patients who have anemia or a history of menorrhagia or hypermenorrhea. Patients experiencing menorrhagia and/or metrorrhagia following IUD insertion may be at risk for the development of hypochromic microcytic anemia. Also, IUD's should be used with caution in patients receiving anticoagulants or having a coagulopathy.

f. Syncope, bradycardia, or other neurovascular episodes may occur during insertion or removal of IUD's, especially in patients with a previous disposition to these conditions.

g. Patients with valvular or congenital heart disease are more prone to develop subacute bacterial endocarditis than patients who do not have valvular or congenital heart disease. Use of an IUD in these patients may represent a potential source of septic emboli.

h. Use of an IUD in those patients with acute cervicitis should be postponed until proper treatment has cleared up the infection.

i. Since an IUD may be expelled or displaced, patients should be reexamined and evaluated shortly after the first postinsertion menses, but definitely within 3 months after insertion. Thereafter annual examination with appropriate medical and laboratory examination should be carried out.

j. The patient should be told that some bleeding and cramps may occur during the first few weeks after insertion, but if these symptoms continue or are severe she should report them to her physician. She should be instructed on how to check after each menstrual period to make certain that the thread still protrudes from the cervix, and she should be cautioned that there is no contraceptive protection if the IUD is expelled. She should be cautioned not to pull on the thread and displace the IUD. If partial expulsion occurs, removal is indicated and a new IUD may be inserted.

k. The use of medical diathermy (shortwave and microwave) in patients with metal-containing IUD's may cause heat injury to the surrounding tissue. Therefore, medical diathermy to the abdominal and sacral areas should not be used.

ADVERSE REACTIONS

These adverse reactions are not listed in any order of frequency or severity.

Reported adverse reactions include: endometritis, spontaneous abortion, septic abortion, septicemia, perforation of the uterus and cervix, embedment, fragmentation of the IUD, pelvic infection, vaginitis, leukorrhea, cervical erosion, pregnancy, ectopic pregnancy, difficult removal, complete or partial expultion of the IUD, intermenstrual spotting, prolongation of menstrual flow, anemia, pain and cramping, dysmenorrhea, backaches, dyspareunia, neurovascular episodes including bradycardia and syncope secondary to insertion. Perforation into the abdomen has been followed by abdominal adhesions, intestinal penetration, intestinal obstruction, and cystic masses in the pelvis.

DIRECTIONS FOR USE

(TO BE SUPPLIED BY MANUFACTURER)

Directions for use shall include the following:

1. Insertion technique.
2. Requirements for replacement and removal, if applicable.

CLINICAL STUDIES

Different event rates have been recorded with the use of diffferent IUD's. Inasmuch as these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision. Furthermore, event rates tend to be lower as clinical experience is expanded, possibly due to retention in the clinical study of those patients who accept the treatment regimen and do not discontinue due to adverse reactions or pregnancy. In clinical trials conducted by (name of sponsor) with the (name of IUD), use effectiveness was determined as follows for parous and nulliparous women, as tabulated by the life table method. (Rates are expressed as events per 100 women through 12 and 24 months of use.) This experience is based on (number) women/months of use in-

cluding (number) women who completed 12 months of use and (number) women who completed 24 months of use.

	12 mo		24 mo	
	Parous	Nulliparous	Parous	Nulliparous
Pregnancy				
Expulsion				
Medical removal				
Continuation rate				

(2) Labeling, in sufficient quantities to be available to patients who express interest in IUD's shall accompany each IUD (packaged separately from the sterile packaging), be made available to the patient, and contain the following information:

PATIENT INFORMATION

This brochure provides information on the use of Intrauterine Contraceptive Devices (IUD's). There are other birth control methods that may be suitable. Before deciding which type of birth control method to use, you should read this brochure and have the opportunity to discuss fully with your doctor any questions you may have about the IUD and other methods of contraception.

PREINSERTION INFORMATION

WHAT YOU SHOULD KNOW ABOUT THE IUD

IUD's are small articles of various sizes and shapes which are inserted into the uterus (womb). The purpose of the IUD is to prevent pregnancy.

How the IUD prevents pregnancy is not completely understood. Several theories have been suggested. IUD's seem to interfere in some manner with the implantation of the fertilized egg in the lining of the uterine cavity. The IUD does not prevent ovulation.

The effectiveness of the IUD is measured by the pregnancy rate of women who use it and the rate of adverse reactions and side effects requiring removal of the IUD.

USE-EFFECTIVENESS

Different pregnancy and adverse reaction rates have been reported with the use of different IUD's. Because these rates are usually derived from separate studies conducted by different investigators in several population groups, they cannot be compared with precision.

In Clinical trials with (name of IUD), ——— patients completed ——— cycles or months in use. The incidence of unplanned pregnancies was ——— per 100 woman years or ——— women out of 100 became pregnant in a year while using an IUD. The incidence of adverse reactions requiring medical removal of the IUD is ——— per 100 woman years or ——— women out of 100 discontinued using the IUD for medical reasons.

WHAT YOU SHOULD TELL YOUR DOCTOR

Before you have an IUD inserted, you should tell you doctor if you have ever had, or suspect you have ever had, any of the following conditions which might make the IUD unsuitable as a method of contraception for you:

Abnormalities of the uterus (womb).
Allergy to copper.
Anemia.
Bleeding between periods.
Cancer of the uterus (womb) or cervix.
Fainting attacks.
Heart disease.
Heart murmur.
Heavy menstrual flow.
Infection of the uterus (womb) or cervix.
Pelvic infection (pus in fallopian tubes).
Prior IUD use.
Prior uterine surgery.
Recent abortion or miscarriage.
Recent pregnancy.
Severe menstrual cramps.
Suspected or possible pregnancy.
Suspicious or abnormal ''Pap'' smear.
Unexplained genital bleeding.
Vaginal discharge or infection.
Venereal disease.

ADVERSE REACTIONS

The following adverse reactions and side effects have been reported and may occur after the IUD is inserted:
Anemia.
Backache.
Blood poisoning (septicemia).
Bowel obstruction.
Cervical infection.
Complete or partial expulsion.
Cysts on ovaries and tubes.
Delayed menstruation.
Difficult removal.
Embedment.
Fainting at the time of insertion or removal.
Fragmentation of the IUD.
Intermenstrual spotting.
Internal abdominal adhesions.
Pain and cramps.
Painful intercourse.

Pelvic infection.
Perforation of the uterus (womb) or cervix.
Pregnancy.
Pregnancy outside the uterus (womb) (tubal or ovarian).
Prolonged or heavy menstrual flow.
Septic abortion (infected miscarriage) followed in some cases by blood poisoning (septicemia) which can lead to death.
Spontaneous abortion (miscarriage).
Vaginal discharge and infection.

If you decide on the IUD as your method of birth control, read the following information and instructions carefully. Please keep this brochure so that you may refer to it. If you have any questions, consult your doctor.

POSTINSERTION INFORMATION

DESCRIPTION

(TO BE SUPPLIED BY MANUFACTURER)

Description shall include the following information.

1. Proprietary or established name of the IUD.
2. Model.
3. Physical dimensions (size and shape).
4. Composition (metal or plastic).
5. Color and number of the tail or threads.
6. Other characteristics.

DIRECTIONS FOR USE

1. *Checking your IUD.* A tail or thread is attached to the IUD so that you can check to see if it is still in place since the IUD can come out of the uterus (womb) without your knowing it. This occurs most often during or right after a menstrual period.

Follow these steps to make sure your IUD is in place:

a. Wash your hands.

b. Assume the squatting position or seat yourself on the toilet.

c. Insert the index or middle finger high in vagina and locate the cervix (mouth of the uterus (womb)). The cervix feels firm like the tip of your nose.

d. Feel for the tail or thread of the IUD, which should be in the cervix high in your vagina.

e. If you can feel the tail or thread it is likely that the IUD is in place and working. You should not pull on the tail or thread. This may displace the IUD.

f. After each menstrual period, you should check to make sure the tail or thread is in place in the cervix. You may check for the tail or thread more often if you wish.

g. If you think the IUD has come out or has been displaced (i.e., you cannot feel the tail or thread or you can feel the IUD itself), use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked. (These alternative methods are not as effective as IUD's.) Call your doctor for an examination.

h. You should return to see your doctor as soon as possible after your next menstrual period, after insertion of your IUD, but no later than 3 months after insertion. This will allow the doctor to make sure that the IUD is in the correct position.

i. After your first checkup, you should be checked at least once a year by your doctor.

2. *Continuation and removal.* While you are wearing the IUD, you may use tampons and take douches, if this is your usual practice. With some IUD's, you may wear the IUD until you wish to become pregnant. Check with your doctor concerning this. You should return to your doctor if you wish to have the IUD removed.

SIDE EFFECTS

The following may occur during or after the IUD is inserted:

1. Some bleeding occurs following insertion in most women. Because of this, your doctor may choose to insert your IUD during or at the end of your menstrual period. This also reduces the possibility that you are pregnant at the time of IUD insertion.

2. Bleeding between menstrual periods usually in the form of spotting, may occur during the first 2 or 3 months after insertion. The first few menstrual periods after the insertion may be heavier and longer. If these conditions continue for longer than 2 or 3 months, consult your doctor.

3. Pain, usually in the form of uterine cramps or low backache, may occur at the time of insertion and last for a few days. Simple pain medication usually relieves the cramping.

4. Fainting may occur at the time of insertion or removal of an IUD. This passes quickly and is not usually serious.

5. The IUD may be expelled during the first two or three menstrual cycles following insertion. Expulsion increases the risk of an unplanned pregnancy. Although not as effective as the IUD, the use of a second contraceptive method, such as a contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), is recommended.

WARNINGS

1. Call your doctor for any of the following reasons:

a. *Severe or prolonged bleeding.* If the flow is heavier and lasts much longer than your usual menstrual flow, you may need to have the IUD removed to prevent the development of anemia.

b. *Pelvic pain and cramps.* This could mean an infection has developed requiring treatment.

c. *Exposure to venereal disease (VD).* If exposure to venereal disease is suspected, report for examination and treatment promptly.

Failure to do so could result in serious pelvic infection because use of an IUD in itself does not prevent venereal disease.

d. *Tail or thread disappearance.* If you cannot feel the tail or thread coming through the cervix, it is possible that the IUD has been expelled or displaced or that perforation has occurred. If any of these has occurred you are no longer protected from becoming pregnant. Use another birth control method, such as contraceptive vaginal foam, cream, or jelly, or condoms (rubbers), until you can be checked. (These alternative methods are not as effective as the IUD).

2. Do not undergo medical diathermy (including shortwave or microwave) treatments to the abdomen or lower back areas if you are wearing a metal IUD. these treatments may cause heat injury to the surrounding tissues.

SPECIAL WARNING ABOUT PREGNANCY WITH AN IUD IN PLACE

Some women become pregnant while using an IUD. If you miss your menstrual period, or if you have a scanty flow during your period, or if you suspect that you might be pregnant, see your doctor right away. Serious complication of sepsis (severe infection), septic abortion (infected miscarriage), and death have occurred when a pregnancy continues with an IUD in place. Most of the occurrences of these serious complications have been reported in the middle third of pregnancy.

If your doctor confirms that you are pregnant, he should remove the IUD if the tail is visible. Removal of an IUD in pregnancy decreases the likelihood of serious complications.

If removal of your IUD proves to be difficult, you and your doctor should discuss at that time the question of continuing the pregnancy in view of the serious complications that may occur. In reaching a decision as to whether or not to have an abortion, it should be remembered that the risks associated with terminating a pregnancy increase with the length of time you are pregnant.

(3) Any device IUD that is not labeled as required by this section and that is either introduced or delivered for introduction into interstate commerce, or held for sale after shipment in interstate commerce after November 7, 1977 is misbranded pursuant to section 502 of the act. However, an IUD in the possession of an independent wholesaler, a retailer, or a licensed practitioner before November 7, 1977 is not misbranded if labeling required by paragraph (b)(2) of this section is furnished to such independent wholesalers, retailers, or licensed practitioners in sufficient quantities to accompany each device in their possession.

[42 FR 23780, May 10, 1977; 42 FR 35155, July 8, 1977]

§ 801.430 User labeling for menstrual tampons.

(a) This section applies to scented or scented deodorized menstrual tampons as identified in § 884.5460 and unscented menstrual tampons as identified in § 884.5470 of this chapter.

(b) Data show that toxic shock syndrome (TSS), a rare but serious and sometimes fatal disease, is associated with the use of menstrual tampons. To protect the public and to minimize the serious adverse effects of TSS, menstrual tampons shall be labeled as set forth in paragraphs (c), (d), and (e) of this section and tested for absorbency as set forth in paragraph (f) of this section.

(c) If the information specified in paragraph (d) of this section is to be included as a package insert, the following alert statement shall appear prominently and legibly on the package label:

ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information.

(d) The labeling of menstrual tampons shall contain the following consumer information prominently and legibly, in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use:

(1)(i) Warning signs of TSS, e.g., sudden fever (usually 102° or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;

(ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;

(2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 1 to 17 per 100,000 menstruating women and girls per year,