§ 310.502 Certain drugs accorded new drug status through rulemaking procedures.

(a) The drugs listed in this paragraph (a) have been determined by rulemaking procedures to be new drugs within the meaning of section 201(p) of the act. Except as provided in paragraph (b) of this section, an approved new drug application under section 505 of the act and part 314 of this chapter is required for marketing the following drugs:

(1) Aerosol drug products for human use containing 1,1,1-trichloroethane.

(2) Aerosol drug products containing zirconium.

(3) Amphetamines (amphetamine, dextroamphetamine, and their salts, and levamfetamine and its salts) for human use.

(4) Camphorated oil drug products.

(5) Certain halogenated salicylanilides (tribromsalan (TBS, 3,4,5-tribromosalicylanilide), dibromsalan (DBS, 4′, 5-dibromosalicylanilide), metabromsalan (MBS, 3, 5-dibromosalicylanilide), and 3,3′, 4,5-tetrachlorosalicylanilide (TCSA)) as an ingredient in drug products.

(6) Chloroform used as an ingredient (active or inactive) in drug products.

(7) Cobalt preparations intended for use by man.

(8) Intrauterine devices for human use for the purpose of contraception that incorporate heavy metals, drugs, or other active substances.

(9) Oral prenatal drugs containing fluorides intended for human use.

(10) Parenteral drug products in plastic containers.

(11) Sterilization of drugs by irradiation.

(12) Sweet spirits of nitre drug products.

(13) Thorium dioxide for drug use.

(14) Timed release dosage forms.

(15) Vinyl chloride as an ingredient, including propellant, in aerosol drug products.

(b) Any drug listed in paragraph (a) of this section, when composed wholly or partly of any antibiotic drug, must be certified under section 507 of the act or exempted from certification under section 507 of the act for marketing.

§ 310.502 Intrauterine devices for human use for the purpose of contraception.

(a) New drug status of certain intrauterine devices for human use for the purpose of contraception.

(1) The Food and Drug Administration has become aware of the increased clinical use for the purpose of contraception of intrauterine devices (IUD’s) that incorporate heavy metals, drugs, or other active substances. The amount of local irritation caused by such active materials has been reported as being correlated, in animal studies, to the efficacy of such devices in achieving their contraceptive effect. Several investigators have reported different pregnancy rates which appear to be dependent on the type of metal used and/or the amount of exposed surface of the metal. Drugs have been incorporated with otherwise inert intrauterine devices to increase the contraceptive effect, decrease adverse reactions, or provide increased medical acceptability.

(2) Intrauterine devices used for the purpose of contraception and incorporating heavy metals, drugs, or other active substances to increase the contraceptive effect, to decrease adverse reactions, or to provide...
Food and Drug Administration, HHS

§ 310.502

increased medical acceptability, are not generally recognized as safe and effective for contraception and are new drugs within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act. A completed and signed “Investigational New Drug Application” set forth in part 312 of this chapter) must therefore be submitted to cover clinical investigations to obtain evidence that such preparations are safe and effective for this use. An approved new drug application is required for the marketing of such articles.

(b) Labeling of intrauterine contraceptive devices considered new drugs (drug IUD’s). The intrauterine contraceptive device 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 intrauterine contraceptive devices 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 drugs.

(3) Labeling accompanying each drug IUD and directed to the physician shall be substantially as follows, adjusted where appropriate to the requirements of a particular drug 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 new drug application is in effect.

(NAME OF DRUG 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 endomteritis or infected abortion in the past 3 months.
5. Known or suspected uterine or cervical malignancy including unresolved, abnormal "Pap" smear.
7. Untreated acute cervicitis until infection is controlled.
8. Copper-containing IUD’s should not be inserted in presence of diagnosed Wilson’s Disease.
9. Known allergy to copper. (For copper-containing IUD’s.)

WARNINGS

1. Pregnancy—A. Long-term effects—Long-term effects on the offspring when pregnancy occurs with (name of drug 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 mid-trimester 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 perforation 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.

6. Congenital anomalies. Systemically administered sex steroids, including progestational agents, have been associated with an increased risk of congenital anomalies. It is not known whether such anomalies could occur when pregnancy is continued with a progestational-containing IUD in place.

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 an 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. Therefore, an annual examination with appropriate medical and laboratory examination should be carried out. The IUD should be replaced every years (information to be supplied by manufacturer).

j. The patient should be told that some bleeding and cramps may occur during the first few weeks after insertion, but if her 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. The patient should be told to return in ---- years for replacement of the IUD.

k. The use of medical diathermy (short-wave 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.

l. Copper-containing IUD’s—A copper induced urticarial allergic skin reaction may develop in women wearing a copper-containing IUD. If symptoms of such an allergic response occur, the patient should be instructed to tell the consulting physician that a copper-bearing device is being worn.

**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, embedding, fragmentation of the IUD, pelvic infection, vaginitis, leukorrhea, cervical erosion, pregnancy, ectopic pregnancy, difficult removal, complete or partial expulsion of the IUD, pelvic infection, vaginitis, leukorrhea, cervical erosion, pregnancy, ectopic pregnancy, difficult removal, complete or partial expulsion of the IUD, intermenstrual spotting, prolongation of menstrual flow, anemia, pain and cramping, dysmenorrhea, gastrointestinal symptoms, intestinal penetration, intestinal obstruction, and cystic masses in the pelvis.

For copper-containing IUD’s the following adverse reaction should also be added: urticarial allergic skin reaction.

**DIRECTIONS FOR USE**

**(TO BE SUPPLIED BY MANUFACTURER)**

Directions for use shall include the following:

1. Insertion technique.
2. Requirements for replacement and removal (including information on whether the IUD should be replaced periodically and, if so, how often).

**CLINICAL STUDIES**

Different event rates have been recorded with the use of different 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 drug 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, including (number) women who completed 12 months of use and (number) women who completed 24 months of use.

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<thead>
<tr>
<th></th>
<th>Parous</th>
<th>Nulliparous</th>
<th>Parous</th>
<th>Nulliparous</th>
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<tr>
<td>Pregnancy ...</td>
<td>12 mo</td>
<td>24 mo</td>
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<td>Expulsion ...</td>
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<td>Medical removal .........</td>
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<td>Continuation rate .......</td>
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(2) Labeling, in sufficient quantities to be available to patients who express interest in IUD’s, shall accompany each drug 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.
§ 310.502

In clinical trials with (name of drug 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 your 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 (plus 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.
Venerial disease.
Wilson's 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.
Pelvic infection.
Perforation of the uterus (womb) or cervix.
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 drug 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 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 (e.g., 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 the IUD.) 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
FAILURE TO DO SO COULD RESULT IN SERIOUS PELVIC INFECTION BECAUSE USE OF AN IUD DOES NOT PREVENT VENEREAL DISEASE.

a. 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 drug 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, a drug 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.

(4) The holder of an approved new drug application for such device, as described in paragraph (a)(2) of this section, shall submit
a supplement to his application to provide for the labeling described in paragraphs (b) (1) and (2) of this section. The supplement shall be submitted before November 7, 1977, under the provisions of §314.70 of this chapter. The labeling may be put into use without advance approval by the Food and Drug Administration.

(c) Applicability. Paragraphs (a) and (b) of this section do not apply to the following intrauterine contraceptive devices, which are subject to the requirements of §801.427 of this chapter:

(1) Intrauterine devices fabricated solely from inactive materials, e.g., inactive plastics or metals.

(2) Intrauterine devices 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) Intrauterine devices that contain a component, such as barium, added exclusively for the purpose of visualization by x-ray.

§310.503 Requirements regarding certain radioactive drugs.

(a) On January 8, 1963 (28 FR 183), the Commissioner of Food and Drugs exempted investigational radioactive new drugs from part 312 of this chapter provided they were shipped in complete conformity with the regulations issued by the Nuclear Regulatory Commission. This exemption also applied to investigational radioactive biologics. It is the opinion of the Nuclear Regulatory Commission, and the Food and Drug Administration that this exemption should not apply for certain specific drugs and that these drugs should be appropriately labeled for uses for which safety and effectiveness can be demonstrated by new-drug applications or through licensing by the Public Health Service in the case of biologics. Continued distribution under the investigational exemption when the drugs are intended for established uses will not be permitted.

(c) Based on its experience in regulating investigational radioactive pharmaceuticals, the Nuclear Regulatory Commission has compiled a list of reactor-produced isotopes for which it considers that applicants may reasonably be expected to submit adequate evidence of safety and effectiveness for use as recommended in appropriate labeling. Such use may include, among others, the uses in this tabulation:

<table>
<thead>
<tr>
<th>Isotope</th>
<th>Chemical form</th>
<th>Use</th>
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<tbody>
<tr>
<td>Chromium 51</td>
<td>Chromate</td>
<td>Spleen scans.</td>
</tr>
<tr>
<td>Do</td>
<td>do</td>
<td>Placenta localization.</td>
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<tr>
<td>Do</td>
<td>Labeled human serum albumin.</td>
<td>Red blood cell labeling and survival studies.</td>
</tr>
<tr>
<td>Do</td>
<td>do</td>
<td>Gastrointestinal peptide loss studies.</td>
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<tr>
<td>Do</td>
<td>do</td>
<td>Placenta localization.</td>
</tr>
<tr>
<td>Do</td>
<td>Labeled red blood cells.</td>
<td>Do.</td>
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<tr>
<td>Cobalt 58 or Cobalt 60</td>
<td>Labeled cyanocobalamin.</td>
<td>Intestinal absorption studies.</td>
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<tr>
<td>Gold 198</td>
<td>Colloidal</td>
<td>Liver scans.</td>
</tr>
<tr>
<td>Do</td>
<td>do</td>
<td>Intracavitary treatment of pleural effusions and/or ascites.</td>
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<tr>
<td>Do</td>
<td>do</td>
<td>Intestinal treatment of cancer.</td>
</tr>
<tr>
<td>Iodine 131</td>
<td>Iodide</td>
<td>Diagnosis of thyroid functions.</td>
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<tr>
<td>Do</td>
<td>do</td>
<td>Thyroid scans.</td>
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<tr>
<td>Do</td>
<td></td>
<td>Treatment of hyperthyroidism and/or cardiac dysfunction.</td>
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<tr>
<td>Do</td>
<td>Labeled human serum albumin.</td>
<td>Treatment of thyroid carcinoma.</td>
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<td>Do</td>
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<td>Blood volume determinations.</td>
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<td>Do</td>
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<td>Cisternography.</td>
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<td>Do</td>
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<td>Brain tumor localization.</td>
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<td>Do</td>
<td>do</td>
<td>Placenta localization.</td>
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<td>Do</td>
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<td>Cardiac scans for determination of pericardial effusions.</td>
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<td>Liver function studies.</td>
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<td>Do</td>
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<td>Liver scans.</td>
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<td>Do</td>
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<td>Kidney function studies and kidney scans.</td>
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<tr>
<td>Do</td>
<td>Iodine 131</td>
<td>Fat absorption studies.</td>
</tr>
<tr>
<td>Do</td>
<td>Cholografin</td>
<td>Cardiac scans for determination of pericardial effusions.</td>
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<tr>
<td>Do</td>
<td>Macroaggregated</td>
<td>Lung scans.</td>
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21 CFR Ch. I (4-1-97 Edition)