FDA Registration and Listing

IMPORTANT: Assignment of a registration number and labeler code by the FDA does not constitute approval. Never use your registration or labeler code to advertise that you or your products are "FDA Approved." This will cause your products to be deemed "misbranded."

IMPORTANT: Annual Registration & Drug Product Listing forms are no longer automatically sent to your facility. It is your responsibility to obtain the appropriate forms and update as required.

Introduction

This document is intended to assist medical gas companies, which are required to "register" and "list", in obtaining and submitting the necessary forms to meet the registration and listing requirements set forth in 21 CFR part 207, as authorized or required under section 510 of the Federal Food, Drug, and Cosmetic Act.

FDA's Guideline for Industry covering this subject can be found at the end of this document.

How to get forms

Download the current registration form (FDA Form 2656) and listing form (FDA Form 2657) from www.fda.gov/cder/drls/default.htm

Where to send completed forms

The current address for the drug registration and listing branch will be listed on the forms. Be sure to keep a copy of your submissions. Also, we recommend that you mail the forms with a signature confirmation of delivery.

Drugs / Devices

By definition, medical drug gases are prescription (Rx) drugs, which are intended to be use in the diagnosis, mitigation, treatment, or prevention of disease in man or other animal. Examples include Oxygen USP, Nitrogen NF, Nitrous Oxide USP, Carbon Dioxide USP, Helium USP, and Medical Air USP. Medical device gases are gases or gas mixtures that are used for diagnostic purposes or as component, part, or accessory of a device apparatus. They do not achieve any of their principal intended purposes by chemical action in or on the body or by being metabolized. Examples are blood gas mixtures, medical laser gas mixtures, lung diffusion gas mixtures, and nitrogen refrigerated liquid NF.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Facility Type Terminology

Companies who fill or trans-fill medical drug gases in either compressed gas or liquid form are considered to be "manufacturers". The FDA definition of "distributor" is different from the typical industry definition and does not apply to most medical gas production facilities.

Registration Overview – Drug Manufacturers of medical drug gases must register and list with the FDA within 5 days of beginning operations. Registration is accomplished by completing form FDA 2656, "Registration of Drug Establishment/ Labeler Code Assignment". Subsequent annual registration is required on form FDA 2656. No federal fee is charged for either the initial registration or subsequent annual registrations. However, state boards of pharmacy usually charge a fee for state registration.

Listing Overview – Drugs

When you register initially, you must also submit a drug product listing (DPL) on form FDA 2657. The purpose of this form is to inform the FDA of drug gases you manufacture their package sizes and quantities and provide sample labeling.

Subsequent review and update of DPL's are required in June and December of each year. These are to be used whenever products or package sizes are added or discontinued or labeling has changed. If you have had no changes from the prior listing, you are not required to update.

Copies of your current registration, listing and labeling must be made available for FDA inspection. You can also search the FDA's National Drug Code Directory database to determine if the FDA has a record of your current registration and listing. Go to: http://www.fda.gov/cder/ndc/database/default.htm

Registration Overview – Devices

A company must register its name, places of business and all establishments and list the device gases. This covers companies who manufacture and those that repackage or re-label. Initial registration is on form FD 2891.

Subsequent annual registration is on form FD 2891. There is a Device Establishment User Fee ($1851.00 in 2008.)

Note: Forms are Obtainable from the Center for Devices and Radiological Health (HFZ-342), Food and Drug Administration, 1390 Picard Drive, Rockville, Md. 20850 or any FDA District Office (See Tab 6).

Manufacturers are required to give FDA 90 days notice before they can introduce a device on the market (Sec. 510(k)). During the 90-day period, FDA will determine whether the device is subject to a "pre-market approval application" containing evidence that the device is safe and effective before it may be commercially distributed to the public.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

A pre-market notification (21 CFR Part 807, Subpart E) to FDA must include the following information:

1) The trade and common name of the device;
2) Labeling and advertisements describing the device, its intended use, and directions for use;
3) The classification of the device; and
4) A statement of how the device is either similar to or different from others on the market, with data to support the statement.

In most cases, this pre-market notification is a simple process for the common class 1 medical device gases. Contact your GAWDA FDA Tech Support Consultant if you have any questions.

Private Labeling

A "distributor" (also called, Private Label Distributor) is someone who resells or provides drug products under their own label, but does not fill cylinders.

A distributor must obtain a labeler code and the products he sells must also be listed. A distributor may file a form FDA 2656 to request a labeler code and indicate that he is filing as a "distributor" instead of a manufacturer. He may also file a drug listing or, alternatively, the registered establishment (manufacturer) must list the distributor's drug products by filing a form FDA 2658 (Registered Establishments' Report of Private Label Distributors).

> 21 CFR §207.20(b):
>
> (b) Owners or operators of establishments not otherwise required to register under section 510 of the act that distribute under their own label or trade name a drug manufactured or processed by a registered establishment may elect to submit listing information directly to FDA and to obtain a Labeler Code. A distributor who submits drug listing information shall include the registration number of the drug establishment that manufactured, prepared, propagated, compounded, or processed each drug listed. All distributors who submit drug listing information to FDA assume full responsibility for compliance with all of the requirements of this part. Each such distributor at the time of submitting or updating drug listing information as required under §207.30 shall certify to the registered establishment that the submission has been made by providing a signed copy of Form FDA 2656 (Registration of Drug Establishment) to the registered establishment that manufactures or processes the drug. Each such distributor shall submit the original of Form FDA 2656 showing this certification to FDA, and shall accompany the certification with a list showing the National Drug Code number that the distributor has assigned to each drug product. If a distributor does not elect to submit drug listing information directly to FDA and to obtain a Labeler Code, the registered establishment shall submit the drug listing information. Distributors or registered establishments shall use Form FDA 2658 (Registered Establishments' Report of Private Label Distributors) to submit drug listing information or to request a Labeler Code, or both.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Form FDA 2656

When to register – within 5 days of beginning operations.

Note: Master Blank Form can be found at the end of this document.

Definitions –

Commercial distribution: "Any distribution of a human drug except for investigational use . . . but the term does not include internal or interplant transfer of an active pharmaceutical ingredient between registered establishments within the same parent, subsidiary, and/or affiliate company."

Distributor: "Distributes a product under a custom or own label. The product is manufactured and labeled by a registered establishment."

Establishment: "A place of business under one management at one general physical location."

Labeler/Relabeler: "Establishment which affixes the original label to a product or changes in any way the labeling on a product without affecting the product or its container."

Manufacturing or processing: "manufacture, preparation, propagation, compounding, or processing of a drug or drugs and is the making by chemical, physical, biological, or other procedures any articles that meet the definition of drugs. The term includes manipulation, sampling, testing, or control procedures applied to the final product or to any part of the process. The term also includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package to further distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer."

Packer/Repacker: "Establishment packs a product or products into different containers without making any change in the form of the product. This includes packers of raw agricultural products and medicinal gas repackers."

Amendments to Registration

"Changes in individual ownership, corporate or partnership structure, location or drug-handling activity, must be submitted by form FDA 2656 (Registration of Drug Establishment) as an amendment to registration within 5 days of such changes. A change in a registered establishment's firm name within 6 months of the registration of the establishment is required to be supported by a signed statement of the establishment's owner or operator that the change is not made for the purpose of changing the name of the manufacturer of a drug product. Changes in the names of officers and directors of the corporations do not require such amendment but must be submitted at time of the annual registration."

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Drug Listing
(Form FDA 2657)

When to list – within 5 days of beginning operations (include with your registration form, FDA 2656)

Note: Master Blank Form can be found at the end of this document.

National Drug Code – The NDC is comprised of three parts: a labeler code, product code, and package code.

Labeler Code –The FDA will assign your labeler code when they verify your registration and return to you via mail. This will be your permanent labeler code for your facility. Leave this area blank for first time registration.

Product Code – The product code is a code you assign to identify the particular drug gas you are listing (see blocks 90-93). It is a number of your own choosing and must be either four digits or, using a leading asterisk (*), three digits. See below.

Package Code – The package code (see blocks 21-22) is a code you assign to identify package (cylinder) sizes. It is a number of your own choosing and must be either two digits or, using a leading asterisk (*), one digit. See below.

Product Code/Package Code – The combination of Product Code and Package Code must comprise a total of 5 numbers. Therefore, you may use a 4/1 or 3/2 combination. For example:

Product code Package Code
*123 10 ---- example of 3/2 combination
1234 *1 ---- example of 4/1 combination

Once you have chosen a Product/Package Code configuration (4/1 or 3/2), the same configuration must be used in assigning the Product/Package Code for all drugs listed.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Drug Product Listing
Form FDA 2657 Instructions

This form is used by all registrants to submit a listing for every product in commercial distribution, and private label distributors who elect to submit listing information to FDA for products they distribute. This form is also used to provide updates to product listing information every June and December or at the discretion of the registrant, when any change occurs. We recommend submitting forms as soon as possible once a change occurs so that the information on prescription drug products can be correctly reflected in *the National Drug Code Directory*. There are five basic reasons for submitting this form:

1. To report the marketing of a **new drug** not reported previously
2. To report the **discontinuation** of all marketing of a drug previously listed
3. To report the **start of marketing** of a drug previously discontinued.
4. To **modify or add** to the information concerning a drug previously listed, (see CFR 21, 207(a)(3)) and
5. To submit **revised labeling** for a product (see CFR 21, 207(a)(3)) previously listed

Initial Drug Product Listing - Form FDA 2657

Form FDA 2657 (Drug Product Listing) is currently available on the Internet. This form can be obtained from www.hhs.gov/forms

☞ Print or type all entries in English.

☞ Use additional copies of this form for supplemental pages if necessary. Indicate sequential page numbers on the lower right hand corner, if additional pages are used. Supply the following data on all additional pages: full name and address of the reporting firm, Labeler Code and Product Code numbers.

☞ **Do not** write any information in the "FDA USE ONLY" fields.

☞All submissions should include current labels and/or package inserts. Do not submit plastic or glass containers.

☞ A Sample Form FDA 2657 for Gas Companies is available for use.

☞ The Company must provide complete and accurate information on the Form FDA 2657 for a product to be listed by the Agency. A prescription drug product does not appear in the *National Drug Code* directory, if the submission is incomplete.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Col. Unnumbered - ***Name and Site Address of Firm***. Enter the firm's full name and the compliance address. (Form deficiencies will be mailed to this address. However, all deficiencies for foreign firms will be mailed to US agents address.)

Col. 1-5 - ***Control No.*** - FOR FDA USE (Leave Blank)

Col. 6-15 - ***Record ID*** - FOR FDA USE (Leave Blank)

Section 01

Col. 16-17 - ***Sec 01*** - Preprinted

Col. 18 - ***S*** - (Leave Blank)

Col. 19 - ***U*** - Update. Use to indicate a change in information previously submitted. Use the following codes:

C To indicate **change**
E To **correct** errors in information in this section, or
D To **discontinue** product

Col. 20-83 - ***Product Trade Name*** - Enter the trade name of the product as it appears on the label in these 64 spaces. Use acceptable abbreviations when the trade name is too long. Do not include, the USP, NF, or firm name. Leave one space between words. Punctuation is NOT allowed.

Col. 84-89 - ***National Drug Code Labeler Code*** - Using leading zeros, enter the 4-digit or the 5-digit National Drug Code (NDC) Labeler code (assigned by FDA) for the firm. Enter the last digit of the code in Col. 89. If no code has been assigned, leave the field blank. (If you are a first time registrant and no code has been assigned, form FDA 2656 must be submitted to obtain a Labeler code number).

Col. 90-93 - ***National Drug Code Product Code*** - The product code uniquely identifies the drug product formulation of an individual firm. If a 4-digit NDC labeler code has been assigned, use the 4-digit product code/2-digit package code configuration for all products. When a 5-digit Labeler Code has been assigned, choose either of the following Product/Package Code configurations:

3-digit Product Code/2-digit Package Code
or
4-digit Product Code/1-digit Package Code

All positions must be filled in the NDC Product field (Col. 84-93). So, when entering 3-digit product codes, insert an asterisk (*) in the left-most position (Col. 90). Example: *463. When entering 4-digit product code, enter 0463 beginning in the left-most position

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

(Col. 90) (A firm can assign up to a 1000 product code numbers and up to 100 package code numbers by choosing 5-3-2 configuration and can assign up to 10,000 product code numbers and up to 10 package code numbers by choosing 5-4-1 configuration).

NOTE: Once a Product/Package Code configuration is chosen, the same configuration must be used in assigning the Product/Package Code for all drugs listed. Only one product code to specific drug formulation and dosage form should be assigned. If a change only in the trade package is involved, add a new package code without assigning a new product code.

If the product name, dosage form, strength, concentration, or an active ingredient is **changed**, the original product must be discontinued on the Form FDA 2657 and a second Form FDA 2657 must be submitted to list the new product with a new product code.

Col. 94-99 - ***FDA Application No.*** - If this is a prescription product, enter the New Drug Application (NDA), or the abbreviated New Drug Application Number (ANDA), or Biologic License Application Number (BLA) which has been approved for the product in commercial distribution. Enter the number with the last digit in the right-most position using leading zeros when necessary. Do not use hyphens (-). The NDA/ANDA/BLA number is a required number that is needed to complete the listing of the product. If you do not have a NDA/ANDA/BLA number or have not applied for and received one write "NONE" in this field, and your product will be filed as pending, unless:

(a) You submit the product's NDA, ANDA, or BLA number
(b) You declare that the drug product is in compliance with the pre-1938/1962 grandfather provisions, ***you will need to submit documentation to justify your claim that your product does not need an approved application prior to marketing, if requested by the agency,***
(c) Product is subject to a pending DESI Less-than-Effective Federal Register notices,
(d) Product is an Active Pharmaceutical Ingredient (API)
(e) Product is a homeopathic product,
(f) Product is a medical gas,
(g) A kit that does not require an approved application.

If your product is an over-the-counter (OTC) product, enter the Monograph number (21 CFR paragraph number in which monograph has been published). If your OTC product is not covered by a final OTC Monograph, write "NONE." Your OTC product will be filed as pending until you submit the appropriate Monograph number or an Approved Application Number.

Col. 100-105 - ***Report Date*** - Enter the month, day and year on which this form is completed. Example: If completed on May 15, 1993, the entry would be: 51593

Col.106 - ***Type Report*** - (Leave Blank)

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Col. 107-111 - ***Type of Business*** - Enter one or more of the following codes to indicate the business function as it relates to the listed drug: (Start in Col. 107)

Codes

D Private Label Distributor
L Labeler/Relabeler
M Manufacturer
R Repacker

If the business type is not included in the above list, specify the type in the space right of Col. 111 ("Other").

Col. 112-116 - ***Product Type*** - Enter one or more of the following codes. (Start in Col. 112)

Codes

E Allergen/Bacterial/Venom/Vaccine
N Antibiotic
K Blood Products/Factors
O Botanical Product
C Combination Product Kit (2 or more parts)
G Compressed Gas
X Device
L Dialysis Solution
Y Export Product
J Generic Drug Product
M Homeopathic Product
H Human Drug
Z Imported Product
P Large Volume Parenteral
F Preservative Free Product
W Radiopharmaceutical
S Sugar Free Product
U Unspecified
A Veterinary Drug (finished dosage form)
T Vitamin or Vit Contain Product

Col. 117 - ***BNDD*** - (Leave Blank)

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Col. 118 - ***Legal Status*** - Enter an **O** (OTC Drug), **R** (Prescription Drug) or I (Investigational Drug).

Col. 119 - ***Sched (DEA Schedule)*** - If the product is a scheduled drug, enter the appropriate number 1 through 5 to indicate the current DEA schedule for the product, as defined in the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Col. 120 - ***Prof Use*** - An optional category for use on products whose labeling carries statements such as "For Professional Use Only," "For Prescription Compounding," etc. If this applicable, enter the letter **P**.

Col. 121-125 - ***Reason Product Discontinued*** - Enter one of the following codes, starting in Col. 121. If none of these codes is applicable, specify reason in space titled "Other."

Codes

N Discontinued NDC
D Drug Efficacy Study Implementation
F FDA action other than NDA withdrawal
M Lack of marketing interest
W NDA Withdrawal

Col. Unnumbered - ***Basis of Concentration*** - Enter the unit in which the quantity of an ingredient is expressed. If the drug is in unit dosage form (capsule, tablet, or other solid dosage form) enter only the dosage form code. (Use codes in Table I, see Table of Contents). If the drug is not in unit dosage form, the statement of quantity of an ingredient shall express the amount in a specific unit of weight or measurement of a drug (I.E., 5 ml, 1G). Do not use commas when entering whole numbers or decimal points when entering decimal numbers (i.e., enter whole numbers in whole number field and decimal numbers in decimal field).

Col. 126-133 - ***Whole Numbers*** - Enter the whole number beginning in the right-most column and working left. For example, if a liquid preparation states on the label that "X" mg of an ingredient is contained in 4.5 ml of the liquid, the number 4 would be placed in Col. 133, and the number 5 would be placed in Col. 134.

Col. 134-137 - ***Decimal*** - Enter the decimal part of the number starting in Col 134.

Col. 138-140 - ***Unit*** - Enter the unit in which the quantity of an ingredient is expressed. For example, enter **ML** in the unit field starting in Col. 138.

Col. 141-143 - ***Dosage Form*** - Enter the dosage form using codes from Table I , Annex D.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Col. 144-156 - ***Routes of Administration*** - Enter the 3 most frequent routes of administration, starting in the left-most column of each field, using codes from Table II, Annex D. If additional routes exist, enter **"X"** in Col 156, "Other."

Col. 157-158 - ***PT (Part)*** - If the product listed is a combination of 2 or more parts, or 2 or more different dosage forms, a form is required for each part or dosage form. Enter 1 in this field for the first part, 2 for the second, etc. The numbers used in these columns must be the same number that is entered in Section 05 PT (Part) field (Col.21-22).

Col. 159-164 - ***Initial Marketing Date*** Enter the month and year during which the product submitted on this form was first marketed by your firm Example: Enter July 1962 as 71962

Col. 165-170 - ***Most Recent Marketing Date*** - Enter the month and year during which commercial distribution was resumed for previously discontinued product. Example: Enter July 1973 as 071973

Col. 171-176 - ***Discontinued Date*** - Enter the month and year in which commercial distribution of the product was discontinued. Example: Enter May 1967 as 51967.

Section 03

Col. 16-17 - ***SEC*** - Preprinted with 03

Col. 18 - ***S*** - (Leave Blank)

Col. 19 - ***U*** - Use this field when updating package information. Enter the following codes:

D Deleting a package size and type
C Changing a package size and type
E Correct an error

When using **D, C**, or **E**, enter the package size and type in Col. 23-72. Use **C** or **E** to change or correct package **size and type** but NOT to correct package **codes** (Col 21-22). When changing package codes, use **D** to delete the old package code and re-enter the new code, package size and type on a second line.

Col. 20 - ***Smpl (Sample)*** - Enter **S** if the Package Code is for a sample.

Col. 21-22 - ***Pkg Code (Package Code)*** - The Package Code is either the final digit or the final set of 2-digits in the 10-digit NDC Code and identifies the package size and type. The Package Code is assigned by the manufacturer or private label distributor. If the package code is a single digit, enter an asterisk (*) in Col.21 and the code number in Col. 22. For domestic bulk drug substances or Active Pharmaceutical Ingredient (API) enter

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

the numeric one or two digits, or 1 or 2 asterisks (**) as the package code in Col. 21-22. (A bulk drug substance or Active Pharmaceutical Ingredient (API) is any substance represented for use in a drug and when in the manufacturing, processing, or packaging of a drug becomes an active ingredient of a finished dosage form. This does not include intermediates used in the synthesis of such substances.)

Col. 23-47 - ***Package Size*** - The Package Size entry will describe the unit or number of units which make up a package. A package is an entity which cannot be broken or subdivided. It should be entered as described in the manufacturer's or private label distributor's catalog. Some representative package sizes might be 12's, 24's, 100's, etc., for products like tablets, capsules, and ampules. Representative sizes for liquid preparations might be 30 ml, 120 ml, 8 fluid ounce, etc. Do not use commas when entering amounts and do not punctuate abbreviations. Start all entries in Col. 23. Use additional Forms FDA 2657 if more than 5 package sizes are entered. On each additional page, enter the firm name, address, labeler Code, product Code and number each page at the bottom right.

Col. 48-72 - ***Package Type*** - Enter code from Table IV (Annex D) for container in which the product is packaged (i.e., box, bottle, injection, vial, etc.) for each package size. Use additional Forms FDA 2657 if more than 5 package types are entered. On each additional page, enter the firm name, address, labeler Code, product Code and number each page at the bottom right.

Section 05

Col. 16-17 - ***SEC*** - Preprinted with 05

Col. 18 - ***S*** - (Leave Blank)

Col. 19 - ***U*** - This is an update field and is used for error correction, deletion, or change of data previously submitted in Section 05. Enter one of the following:

E correct an error

D delete an item

C change an item previously submitted except active ingredient data and the labeled amounts

When using **E**, **D**, or **C** make sure you enter the data for the other columns on that line.

A change in an active ingredient and/or its labeled amounts, except if in error, requires you to discontinue the product on a Form FDA 2657. Submit a second Form FDA 2657 with an assignment of a new product code.

Col. 20 - ***Type*** - Enter the code that describes the type of data being entered per line in Col. 44-107 of Section 05. If an ingredient is expressed in equivalent amount, enter "**X**"

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

in Col. 20 (see details below under Code **X**). If an ingredient has two equivalent amounts, enter the first as explained above, and for the second equivalent amount, enter "**Y**" in Col. 20 (see details under Code **Y**).

Codes

A Active Ingredient (using established name)

B Biologic Proper Name

X First equivalent ingredient in terms of which the actual ingredient is expressed (e.g., hydrocortisone succinate equivalent to hydrocortisone). Enter the actual ingredient (Col. 44-107) with a code **A** (Col. 20) on one line and the equivalent ingredient on the following line (Col. 44-107) with a code **X** in (Col. 20) and the equivalent amount in the Amount and Unit field (Col. 29-43).

Y Second equivalent ingredient in terms of which the active ingredient is expressed. Following the first equivalent, enter the second equivalent name (Col. 44-107) with a code **Y** in (Col. 20) and equivalent amount in the Amount and Unit fields (Col. 29-43).

I Inactive Ingredient.

Col. 21-22 - ***PT (Part)*** - If the product listed is a combination of two or more components (i.e., two different tablets or a tablet and capsule) enter a 2-digit number in this field for each part of the product beginning with 1. All ingredients for one component would have the same part number. The number used in these columns must be the same numbers entered in Section 01, PT (Part), Col. 157-158). All inactive ingredients should be listed last. Enter part numbers with the last digit in (Col. 22) using leading zeros when necessary.

Col. 44-107 - ***Ingredient(s), and/or Established Name of Product, and Biologic Proper Name*** - Starting in Col. 44, enter active ingredient(s), inactive ingredient(s), and biologic proper name(s) starting in Col. 44 using minimum abbreviations, no punctuation and leave one space between words. Use only one line to enter name.

Biologic Proper Names, as established by FDA, should be entered. The term "established name" with respect to a drug or ingredient means:

1. The applicable official name designated pursuant to Section 508 of the Federal Food, Drug and Cosmetic Act.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

2. If there is no such name or drug, or the ingredient is an article recognized in an official compendium, then the official title in the compendium will be used.
3. If neither 1 or 2 applies, then the common or usual name, if any, will be used.

Col. 23-28 - ***Ingredient No. FOR FDA USE*** - (Leave Blank)

Col. 29-40 - ***Amount*** - Enter the whole number amount of the stated ingredient in Col. 29-36 with the last digit of the number in the right-most column of the field. Enter the decimal part of the number in Col. 37-40 starting in Col. 37.

Enter an amount for an established product name only when applicable.

Col. 41-43 - ***Unit*** - Use codes from Annex, D, Table III in this field.

When reporting inactive ingredients which are added in a quantity sufficient to reach a certain measure, enter "**QS**" in the Unit field starting in Col. 41. When inactive ingredient quantities are not given, enter "**NS**" in the Unit field in Col. 41.

Section 07

(Note: The first line in this section should include your company information. The second line should include the information of the company from which you receive your raw product.)

Col. 16-17 - ***SEC*** - Preprinted with 07

Col. 18 - ***S*** - (Leave Blank)

Col. 19 - ***U*** - Update. Use to indicate a change in information previously submitted. To change any data in this section, enter a "**D**" in Col. 19, and enter the Site or Firm Establishment Reg. No. in Col. 20-26. This will delete the previously submitted line entry. Use the next line to enter the correct information, leaving Col. 19 blank.

Col. 20-26 - ***Site or Firm Establishment Reg. No.*** -This is the number assigned by the FDA to each site where the drug product listed is manufactured. If you have no Registration Number, enter the Manufacturing Site Name, address in Col. 27-66. and NDC Labeler Code in Col 79-84. (Currently registration numbers consists of either 7 digits and/or 10 digits. Use the available space to fill in the 10 digit registration number)

Col. 27-66 - ***Actual Manufacturing Site of the Above Drug Product*** - Enter the full name of the manufacturing site and address which corresponds with the Establishment Reg. No. in Col. 20-26.

Col.67-68 - ***State*** - Enter the two-letter state code of the U.S. Postal Service states and territories (Section G, Abbreviations) for the manufacturer's site address. For foreign firms leave it blank.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Col. 69-78 - ***Foreign Country*** - Enter the foreign country, if applicable, for the site address of the manufacturer. Abbreviate as necessary.

Col. 79-84 - ***NDC Labeler Code*** - Enter the National Drug Code (NDC) Labeler Code assigned by FDA to the registered establishment. Enter with the last digit in the right-most column using leading zeros where necessary.

Col. 85-99 - ***Short Name*** - (Leave Blank)

How to update Product Listing Information

After submitting initial drug listing information, registrants and, if applicable, private label distributors must update their listing information by using Form FDA 2657 every June and December, or at the discretion of the registrant, when any change occurs, in accordance with section 510 of the Act and 21 CFR part 207. We recommend submitting forms as soon as possible once a change occurs so that the information can be correctly reflected in *the National Drug Code Directory*.

To report any changes to listing information, registrants and private label distributors should complete the following fields on Form FDA 2657:

· Name and Address of Firm
· Product Trade Name
· National Drug Code (Labeler, Product)
· Other sections of the form where changes have occurred

Table I - Dosage Forms

Code	Translation
064	GAS

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Table II - Routes of Administration

Code	Translation
038	DENTAL
136	INHALATION, NASAL
002	INTRAVENOUS
014	NASAL
059	NERVE BLOCK
312	NOT APPLICABLE
095	ROUTE NOT GIVEN

Table III - Unit Codes

Code	Translation
FTC	FEET, CUBIC
GAL	GALLON
GM	GRAM
L	LITER
MIS	MISCELLANEOUS
OZ	OUNCE
PKG	PACKAGE
%VV	PERCENT VOL./VOL.
%WV	PERCENT WT./VOL.
%WW	PERCENT WT./WT.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Table IV- Package Type Codes

Code	Translation
CYL	CYLINDER
DEW	DEWAR
NS	NOT STATED
PKG	PACKAGE
TANK	TANK

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Registered Establishments' Report of Private Label Distributors Form FDA 2658 Instructions

This form is used by manufacturers reporting listing information for those private label distributors that do not elect to submit listing information directly to FDA. There must be a Form FDA 2658 for each product processed for one or more firms and sold under the private label distributor's trade names. This form is also used to provide updates to product listing information every June and December or at the discretion of the manufacturer, when any change occurs. We recommend submitting forms as soon as possible once a change occurs so that the information on prescription drug products can be correctly reflected in *the National Drug Code Directory*.

Initial Drug Product Listing - Form FDA 2658

Form FDA 2658 (Registered Establishment' Report of Private Label Distributors) is currently available on the Internet. This form can be obtained from www.hhs.gov/forms

☞ Print or type all entries in English.

☞ Use additional copies of this form for supplemental pages if necessary. Indicate sequential page numbers on the lower right hand corner, if additional pages are used. Supply the following data on all additional pages: full name and address of the reporting firm, Labeler Code and Product Code numbers.

☞ **Do not** write any information in the "FDA USE ONLY" fields.

☞All submissions should include current labels and/or package inserts. Do not submit plastic or glass containers.

☞ The Company must provide complete and accurate information on the Form FDA 2658 for a product to be listed by the Agency. A prescription drug product does not appear in the *National Drug Code* directory, if the submission is incomplete.

Line 1 - (unnumbered)

Col. 1-5 - ***Control No.*** FOR FDA USE - (Leave Blank)

Col. 272/27-311 - ***Reporting Firm*** - Enter the full name of the reporting firm (manufacturer). This should be the same as shown on Form FDA 2656 for the reporting firm. Abbreviate if necessary but NO punctuation.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Col. 312/20-318 - ***Establishment Registration No.*** - Enter the Drug Establishment Number for the manufacturing site of the product.

Col. 251/79-256 - ***Reporting Firm NDC Code*** - Enter the Registered Establishment's National Drug Code (NDC) Labeler and Product Code for the identical product listed on Form FDA 2657.

Line 2 - Site Address

Col. 101-138 - ***Number and Street*** - Enter street number and name or rural route number of the actual location of the site.

Col. 139-158 - ***City*** - Enter the city of the actual location of the site.

Col. 159-160 - ***State*** - Enter the two-letter state abbreviation used by the U.S. Postal Service. (See Annex C for abbreviations.)

Col. 161-165 - ***Zip Code*** - Enter the zip code of the actual location of the site.

Col. 166-175 - ***Foreign Country*** - (Leave Blank)

Col. 14/100 - ***Rprt Date*** - (Report Date) - Enter the month and year in which you completed this form using leading zeros where necessary.

Line 3 - Mailing Address

If the mailing address is different from the site address, complete each field of Line 3 using the same instructions as for the site address. (All correspondence regarding the products listed on this form will be sent to the Site Address or to the mailing address, if different.)

Line 4

Col. 6-15 - ***Record ID FOR FDA USE*** - (Leave Blank)

Section 01

Col. 16-17 - ***SEC*** - Preprinted with 1

Col. 18 - ***S*** - (Leave Blank)

Col 19 - ***U*** - This is an update field. To discontinue a product, enter a "**D**" and complete Line 1 (unnumbered), Line 2 and Line 3; and Line 4, Col. 20-83; and, Line 5 Col 40/84-93 of SEC 01. A product name change requires a new NDC Product Code and a new listing.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Col. 20-83 - ***Trade Name or established Name under which Product is Marketed by Another Firm*** - Enter the trade name of the product as it appears on the label into the allotted space. Use acceptable abbreviations when the trade name exceeds spaces.

Exclude, as part of the product name, USP, NF, or firm name.

Leave one space between words and no punctuation.

Line 5

Col. 40/84 - ***NDC Code*** - Enter the National Drug Code Labeler Code assigned by the FDA to the private label distributor of the drug product being listed. Enter the product code obtained from the private label distributor for the product. (For more information on how to assign product code numbers, see instructions under *Drug Product Listing Form FDA 2657, Col 90-93-National Drug Code Product Code)*

Col. 46-60 - ***Short Name*** - (Leave Blank)

Col. 61-100 - ***Firm Name on Label*** - Enter the name of the firm distributing the drug product listed on the previous line.

Section 03

Col. 16-17 - ***SEC.*** - Preprinted 3

Col. 21-22 - ***Package Code*** - Enter the package codes obtained from the private label distributor for the product. Space has been provided for 5 package codes. Use additional forms for entering additional package codes.

Col. Unnumbered - ***Zip Code*** - Enter the zip code for the distributors site location.

How to update Product Listing Information

After submitting initial drug listing information, manufacturers reporting listing information for those private label distributors must update their listing information by using Form FDA 2658 every June and December, or at the discretion of the registrant, when any change occurs, in accordance with section 510 of the Act and 21 CFR part 207. We recommend submitting forms as soon as possible once a change occurs so that the information on prescription drug products can be correctly reflected in *the National Drug Code Directory*.

To report any changes to listing information, registrants and private label distributors should complete the following fields on Form FDA 2658:
· Reporting Firm Name and Address
· Reporting Firm National Drug Code (Labeler, Product)
· Other sections of the form where changes have occurred

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Guidance for Industry

Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

Additional copies are available from:
Office of Training and Communications
Division of Communications Management
Division of Drug Information HFD-240
5600 Fishers Lane
Rockville, MD 20857
(Tel) 301-827-4573
(Internet) http://www.fda.gov/cder/guidance/index.htm
or
Office of Communication, Training and
Manufacturers Assistance, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike, Rockville, MD 20852-1448
(Internet) http://www.fda.gov/cber/guidelines.htm
Fax: 1-888-CBERFAX or 301-827-3844
Phone: the Voice Information System at 800-835-4709 or 301-827-1800
or
Communications Staff (HFV-12),
Center for Veterinary Medicine (CVM)
7500 Standish Place, Rockville, MD 20855 (Tel) 301-594-1755
(Internet) http://www.fda.gov/cvm/guidance/guidance.html

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
April 2001

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

Procedural

TABLE OF CONTENTS

I. INTRODUCTION
II. BACKGROUND
III. REGISTRATION AND LISTING FORMS
A. Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment)
B. Form FDA 2657 (Drug Product Listing)
C. Form FDA 2658 (Registered Establishments' Report of Private Label Distributors)
IV. INFORMATION UPDATES
A. How to Update Registration Information
B. How to Update Product Listing Information
V. SUBMISSION OF FORMS
VI. HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS -- ESTABLISHMENT REGISTRATION AND LISTING

Guidance for Industry[1]

Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

I. INTRODUCTION

This guidance is intended to assist private label distributors and establishments, which are required to register ("registrants") and list drugs and biological products, in obtaining and submitting the necessary forms to meet the registration and listing requirements set forth at 21 CFR part 207, as authorized or required under section 510 of the Federal Food, Drug, and Cosmetic Act ("the Act") and sections 351 and 361 of the Public Health Service Act. To the extent that information provided in this draft guidance differs from previously disseminated information (e.g. certain information in the Drug Registration and Listing Instruction Booklet), this guidance will supersede any such information when finalized.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

FDA is developing software to make possible the electronic submission of the requisite registration and listing information for drugs and biological products. While this software is being developed, FDA will make establishment registration and listing forms available on the Internet. Since FDA will provide these forms via the Internet, FDA will no longer provide registrants with annual re-registration forms via conventional mail, unless specifically requested. Internet availability of these forms (instead of by conventional mail), until an electronic submission system is fully implemented, is part of an Agency initiative to use modern technology to facilitate the submission of establishment registration and listing information. The Agency plans to propose rulemaking that would revise the requirements on registration and listing, and would require registrants to submit this information electronically.

II. BACKGROUND

Section 510 of the Act and 21 CFR part 207, inter alia, require establishments (e.g. manufacturers, repackers, and relabelers) upon first engaging in the manufacture, preparation, propagation, compounding, or processing of human drugs, veterinary drugs, and biological products, with certain exceptions, to register their establishments and submit listing information for all drugs and biological products in commercial distribution. Registrants are also required to submit, on or before December 31 of each year, updates in registration information for their establishments.[2] Registrants must, at the time of annual registration, also submit required listing information. Additionally, registrants are required to update listing information every June and December of each year to include information for drugs and biological products that have not been previously listed. Certain changes to information for previously listed drugs and biological products must also be submitted every June and December of each year.

Under section 351(j) of the Public Health Service Act (PHS Act), the Act and regulations promulgated under the Act apply to biological products. In addition, section 361 of the PHS Act authorizes FDA to promulgate regulations to prevent the introduction, transmission, and spread of communicable disease. Under this authority, FDA promulgated 21 CFR 207.20(f), which requires manufacturers of those human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated as drugs and/or biological products under the Act and section 351 of the PHS Act to register and list their HCT/Ps using new Form FDA 3356 beginning January 21, 2003.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

III. REGISTRATION AND LISTING FORMS

Various forms have been used to collect registration and listing information. In the past, FDA mailed these forms for industry to complete or, in some cases, verify the information and return. However, these forms are now easily accessible on the Internet. Since the distribution of these forms through the mail is burdensome and time-consuming, the Agency is discontinuing the conventional mailing of the following registration and listing forms:

A. Form FDA 2656 (Registration of Drug Establishment/Labeler Code Assignment)

Since FDA will provide forms via the Internet, FDA will no longer provide annual re-registration forms via conventional mail, unless specifically requested. If registrants would like to receive annual re-registration forms via conventional mail, registrants may direct such requests to the agency contacts designated in this guidance. Additionally, annual re-registration and changes to registration information that, in the past, were reported on Form FDA 2656e should now be reported on Form FDA 2656, in accordance with current regulations. Registrants should review their previous Forms FDA 2656e submitted to the Agency for information reported and contained in FDA's database. If registrants have questions regarding previously submitted information, they should direct inquiries to the appropriate contacts designated elsewhere in this draft guidance document.

Form FDA 2656 is used by:

· Manufacturers, repackers, and relabelers registering an establishment with FDA for the first time. The form must be submitted within 5 days after beginning the manufacture or processing (which includes, inter alia, repackaging and relabeling) of drugs and biological products; alternatively, if the establishment has not previously entered into such an operation, the establishment must register within 5 days after submitting a drug application or biological license application. See 21 CFR 207.21(a).

· Medicated feed mill establishments. Registration must be obtained prior to approval of a medicated feed mill license application. See 21 CFR 515.10.

· Private label distributors obtaining a labeler code.

· Manufacturers, repackers, relabelers, and private label distributors reporting changes in registration information or labeler code information.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

B. Form FDA 2657 (Drug Product Listing)

Form FDA 2657 is used by:

· Registrants reporting the initial listing information for all drugs and biological products in commercial distribution. This form must be submitted within 5 days of beginning the manufacturing or processing of drugs and biological products. See 21 CFR 207.21(a) and 21 CFR 207.22(b).

· Private label distributors that elect to submit listing information directly to FDA.

· Registrants and private label distributors updating listing information for drugs and biological products that have subsequently been introduced for commercial distribution and, therefore, have not previously been listed. This form is also used to report certain changes to information for previously listed drugs and biological products. Any updates must be submitted every June and December or, at the discretion of the registrant, when any change occurs. See 21 CFR 207.21(b), 21 CFR 207.22(b), and 21 CFR 207.30.

C. Form FDA 2658 (Registered Establishments' Report of Private Label Distributors)

Form FDA 2658 is used by:

· Registrants reporting listing information for those private label distributors that do not elect to submit listing information directly to FDA.

· Registrants updating listing information for private label distributors. This information must be submitted every June and December or, at the discretion of the registrant, when any change occurs. See 21 CFR 207.20(b) and 21 CFR 207.30.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

IV. INFORMATION UPDATES

A. How to Update Registration Information

Forms FDA 2656, 2657, and 2658 are available on the Internet at www.fda.gov/cder/drls/registration_listing.htm.

1. To submit annual re-registration information and to report any changes, registrants should complete the following fields on Form FDA 2656:

· Labeler Code

· Registration Number

· Reporting Firm Name

· Reason(s) for Submission (write in "ANNUAL")

· Section D (signature, title, and, date)

· Other sections of the form where changes have occurred

Registrants should **not** complete any other sections where information has remained the same.

2. If there are no changes to report, the following fields should be completed on Form FDA 2656:

· Labeler Code

· Registration Number

· Reporting Firm Name

· Reason(s) for Submission (write in "ANNUAL - NO CHANGE")

· Section D (signature, title, and date)

No other section of the form should be completed.

The Agency encourages submission of annual updates according to the schedule outlined in the current regulations (21 CFR 207.21(a)). However, annual re-registration information must be submitted on or before December 31 of each year, as required by section 510 of the Act.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

It should be noted that since FDA is providing forms via the Internet, FDA will no longer provide registrants with annual re-registration forms via conventional mail, unless specifically requested. If registrants would like to receive annual re-registration forms via conventional mail, or they are unable to download the forms from the Internet, the forms can be obtained by requesting them from the Office of Training and Communications, Division of Drug Information, HFD-240, 5600 Fishers Lane, rm. 12B31, Rockville, MD 20855, (Tel) 301-827-4573. A request for a form using the mail or telephone may take up to 14 days to process. The Agency encourages downloading forms from the Internet, at the Internet address above, to expedite the process.

B. How to Update Product Listing Information

In addition to the forms discussed above, in the past, FDA has periodically mailed to drug establishments a Compliance Verification Report, which is a printout of information from the registrant's listing information previously reported to FDA on Form FDA 2657 or Form FDA 2658. The Agency requested that companies verify or correct the information in the report and return it to the Agency within 30 calendar days of receipt. The Agency considered verification of this information to satisfy the June listing requirement for prescription products.

FDA is discontinuing the mailing of the Compliance Verification Report. After submitting initial drug listing information, registrants and, if applicable, private label distributors must update their listing information by using Form FDA 2657 and/or Form FDA 2658, every June and December, or at the discretion of the registrant, when any change occurs, in accordance with section 510 of the Act and 21 CFR part 207. We recommend submitting forms as soon as possible once a change occurs so that the information can be correctly reflected in *the National Drug Code Directory*.

To report any changes to listing information, registrants and private label distributors should complete the following fields on Form FDA 2657:

· Name and Address of Firm

· Product Trade Name

· National Drug Code (Labeler, Product, Package)

· Other sections of the form where changes have occurred

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

To report any changes to listing information, registrants should complete the following fields on Form FDA 2658:

· Reporting Firm Name

· Reporting Firm NDC Code (Labeler, Product, Package)

· Other sections of the form where changes have occurred

Registrants and private label distributors can consult the *National Drug Code Directory* for a listing of all human prescription drug products listed with the Agency. If a human prescription drug product does not appear in the directory, then FDA will not consider it listed with the Agency. For a product to be listed by the Agency, the company must provide complete and accurate information on the Form FDA 2657 or Form FDA 2658. This directory is available on the Internet at http://www.fda.gov/cder/ndc/index.htm.

V. SUBMISSION OF FORMS

Completed forms 2657 and 2658 for veterinary drugs submitted by mail should continue to go to CVM/OSC/OS/MPIT, HFV-212, 5700 Standish Place, rm. 446, Rockville, MD 20855. All other completed forms submitted by mail should continue to be sent to the Food and Drug Administration, CDER/Drug Registration & Listing, HFD-330, 5600 Fishers Lane, Rockville, MD 20857.

Completed forms FDA 2657 and 2658 for veterinary drugs may be hand carried to CVM/DCU, HFV-199, 7500 Standish Place, rm. N403, Rockville, MD 20855. For all other forms that are being hand carried, they should be delivered to Food and Drug Administration, CDER/Drug Registration & Listing, HFD-330, 5901 B Ammendale Road, Beltsville, MD 20705-1266.

VI. HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS -- ESTABLISHMENT REGISTRATION AND LISTING

On January 19, 2001, FDA promulgated 21 CFR 207.20(f), which requires establishments that manufacture those human cells, tissues, and cellular and tissue-based products (HCT/Ps) regulated as drugs and/or biological products under the Act and § 351 of the PHS Act to register and list their HCT/Ps using new Form FDA 3356 beginning January 21, 2003 (66 FR 5447, January 19, 2001). Until then, such establishments should continue to register and list using the forms and procedures provided in part 207, as discussed above.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.

1 The Office of Compliance and the Office of Information Technology in the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Review prepared this guidance.

2 Failure to register in accordance with section 510 of the Act is a prohibited act under section 301(p) of the Act. Failure to comply with section 510 of the Act renders drugs misbranded under section 502(o) of the Act.

This is information was developed to assist GAWDA members in complying with government regulations; it does not constitute legal advice, and users are advised to obtain legal counsel to develop their individual compliance programs. Additionally, GAWDA does not guarantee that use of this material will ensure compliance with any regulatory or legal standard.