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I. Introduction

A. What is GFDS?

GFDS stands for the Global Formulary Database System, a central data management system designed to maintain product and regulatory information world-wide for the Pfizer Animal Health Group.

B. Levels of Security

GFDS has several levels of security.

Administration level- includes user level security plus the ability to edit code tables.

User level security allows users to input data, add, edit and delete detail level records and produce reports.

Viewer level security allows reporting of information only.

C. About this document

This document provides a step by step guide on how to use the GFDS system.

It is important to note that data contained in the sample screens is only there as an example, and has no relevance to data or products.

This document assumes that the user of the GFDS system is familiar with the technical terminology. This document only provides information about the use of the system.

D. A Note About Date Fields

Date fields in this system take on the form:

DD/MMM/YYYY

DD represents the day. Insert a zero before single digit dates. Eg: 01/JAN/1995

MMM are the first three letters of the month:

JAN, FEB, MAR, APR, MAY, JUN, JUL, AUG, SEP, OCT, NOV, DEC.

Note that for most months, only a single letter is required and the system fills in the rest (minimum requirements denoted by underline above).

YYYY is the complete year. Do not type just 98 or 97, you need to input the four digits.

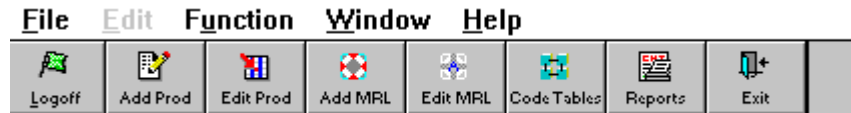
II. How do I access GFDS?

1. Click on the icon/shortcut provided on your desktop to access the database.
2. You will see the screen below:



Figure 1- First Screen When Entering GFDS

3. Click the Logon button to access the logon window. You will then be prompted for your assigned user name and password
4. Enter your username and password.
5. The next thing you will see are the screen selections below:



The menu choices above the buttons provide some of the same functions provided by the buttons and allow the user to choose the location of the tool's bar.

The **File** menu includes Logoff, Toolbars and Exit.



Figure 2- The File Menu

The **Toolbars** selection within the **File** menu allows the user to place the buttons anywhere on the screen. The default position is along the top, but the user can change this so the buttons appear on the side, bottom and as a floating tool bar using the panel below:

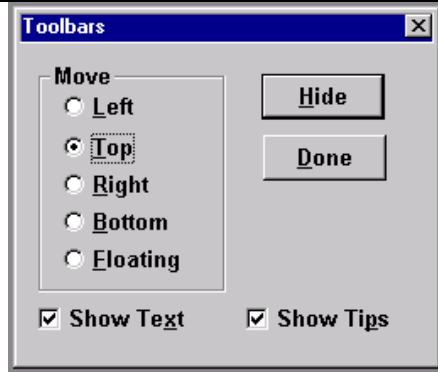










Figure 3- Toolbars Selection Panel

The **Functions** menu can be used instead of the function buttons.



Figure 4- The Function Menu

Below is a list of toolbar button definitions:

	LOGOFF	Click to log off the system
	ADD PRODUCT	Click to add a new product to the system database
	EDIT PRODUCT	Click to edit a product that is in the database
	ADD MRL	Click to add a Minimum Residue Level record
	EDIT MRL	Click to edit a Minimum Residue Level record
	CODE TABLES	Click to edit the Code Tables. (Administration Level Security)
	REPORTS	Click on this button to create and print special reports.
	EXIT	Click here to exit the system.

III. Adding or Editing Products

Selecting Add Prod or Edit Prod results in a similar series of tab screens that allow the user to input all of the related data for that product.



To Edit existing data use the  button. This will bring up the following screen:

The screenshot shows a 'Product Selection' window with the following fields and options:

- Search by:**
 - Region: ASIA
 - Market: Australia
 - Product Name: Decto*
- DM #:** [Empty text box]
- Sort by:**
 - Region
 - Market
 - Product Name
- Buttons:** Run Query, Reset

Figure 5- Product Selection Window


You must select a Region. Select search criteria using a combination of Region, Market, and/or Product Name (a wildcard can be used, e.g. Decto*.)

You can then click Run Query to list all the products in that region or narrow the search by selecting a product name and/or a market. The listing will look as follows:

Region	Market	Product Name	Trade Name
ASIA	Australia	AMOXIL TABLETS 200 MG	AMOXIL TABS 200MGZ
ASIA	Australia	AMOXIL TABLETS 50 MG	AMOXIL TABS 50MG
ASIA	Australia	AMPICLOX LACTATING COW	AMPICLOX LC
ASIA	Australia	AVIAX 5% PREMIX (MYCELIAL)	AVIAX 5% PREMIX
ASIA	Australia	CALF-GUARD	BCASDASD
ASIA	Australia	CLAVULOX DROPS	CLAVULOX DROPS
ASIA	Australia	CLAVULOX READY-TO-USE	CLAVULOX INJECTABLE
ASIA	Australia	CLAVULOX TABLET 250 MG	CLAVULOX TABLETS 250 MG
ASIA	Australia	CLAVULOX TABLET 50 MG	CLAVULOX TABLETS 50MG

Figure 6- Query Results Window



Double-click on the selection or click once and then click the  button to select the product you want.

Both operations will bring up a similar series of tabbed screens. The only difference is that the bar above will say Add product, when you are in the Add mode, and Edit Product, when you are in the edit mode. Otherwise, each screen is identical.

A. The Toolbar Buttons



This toolbar appears when adding or editing a product record.

In addition to the standard buttons, this tool bar contains the following additional buttons. Note that all of the functions in the toolbar can also be accessed by clicking Function on the upper menu bar.

SAVE	Saves the current data in the all tab pages.
DELETE	This deletes all data on the tab page. (Caution, if on you click the top level delete button while on the Product tab, you will delete all associated data.)
RESET	This button allows you to undo any changes prior to saving.

B. The Product Tab


The first tab allows you to enter or edit **Product Information**. When adding, this tab must be filled out before you can proceed to the other tabs.


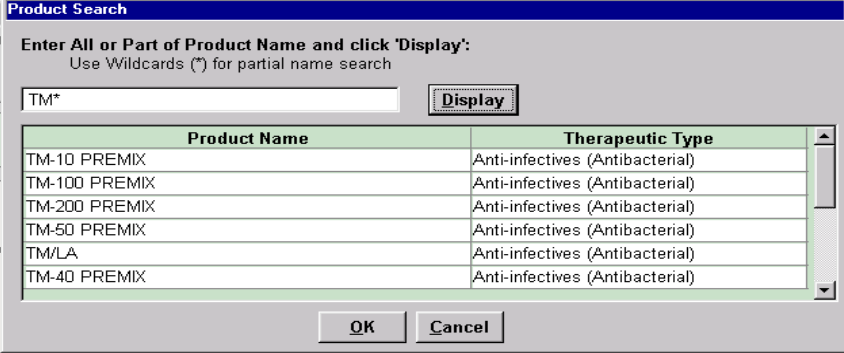


The screenshot shows the 'EDIT PRODUCT' window with the following fields and values:

- Region:** Latin America
- Market:** Venezuela
- Product Name:** TM/LA
- Therapeutic Type:** Anti-infectives (Antibacterial)
- Trade Name:** EMINCIA L.A. INYECTABLE 200 MG/ML
- Dosage:** Liquid, sterile
- Commercial Status:** Non Commercial Commercial
- Comments:** (Empty text area)

Figure 7- The Product Tab

Below is a list of field definitions for the upper and lower portions of the screen:

UPPER PORTION	
REGION	Click on this field's down arrow  to access the pick list of regions, such as North America, Europe, etc. Click on the selected region.
MARKET	Click on the market within that region. For example, in North America, markets are Canada and United States. Click on the desired market for that product.

LOWER PORTION	
PRODUCT NAME SELECTION	<p>There are over 1000 products in the database. To select a product, click on the  button. This will bring up a subscreen.</p>  <p style="text-align: center;"><i>Figure 8- Subscreen for searching for the product name, within the Product Tab.</i></p> <p>To find products that start with the letters TM type: TM*</p> <p>Click .</p> <p>Click on one of the products to select it, then click the OK button.</p>
THERAPEUTIC TYPE	This field is filled in automatically when the product is selected.
TRADE NAME	Enter the trade name for this product in the selected market.
DOSAGE	Enter the dosage required for this product. Click the  down arrow to select from a pick list.
COMMERCIAL STATUS	Click on one of the radio buttons to indicate whether the product is commercial or non-commercial
<p>Commercial Status: <input type="radio"/> Non Commercial <input type="radio"/> Commercial</p>	
COMMENTS	Enter any comments about the product.

C. Registration Tab

When you have completed the product information screen, click on the Registration Tab. This will bring up this screen:

The screenshot shows the 'EDIT PRODUCT' window with the 'Registration' tab selected. The form contains the following fields and values:

- Region: Latin America
- Market: Venezuela
- Product Name: TM/LA
- Trade Name: EMINICIA L.A. INYECTABLE 200 MG/ML
- Initial Registration: 03/JAN/1996
- Renewal Registration: 03/JAN/2001
- Current Label on file at HQ:
- Species Specific Reg #:
- Species: Broiler Chicken
- Regulatory Status: Registered
- Registration Num: 6006
- Prescription: Over the Counter
- Submission Dates: Anticipated: [] [], Actual: 00/ /0000
- Approval Dates: Anticipated: [] [], Actual: 00/ /0000



A callout box points to the 'Add' button with the text: "there can be more than one species for each product. Press the ADD button to continue to add species".




Figure 9- The Registration Tab



Below is a list of fields in the upper and lower portions of the screen:

UPPER PORTION	
REGION, MARKET, PRODUCT NAME TRADE NAME	These fields are filled in by clicking on the Product tab. They can't be modified within this screen
SPECIES SPECIFIC REGISTRATION #	If the registration for this product is specific for species, the check box is checked. This will allow you to enter the Registration Number on this screen. Uncheck this option to enter the Registration Number in the Presentation tab.
INITIAL/RENEWAL REGISTRATION	Enter here initial or renewal registration dates.
CURRENT LABEL ON FILE AT HQ	Indicate whether this particular product label is on file at Pfizer Headquarters (HQ). Enter Y for yes or N for no in this field.
COMMENTS	Enter the comments about the product.

Each product registration can apply to many species. The lower portion of the screen is used to enter species registration data.

The  (Add) and  (Delete) buttons allow you to add or delete registration details

LOWER PORTION	
SPECIES	This field allows you to pick a given species for registration details. Click the down arrow  to select a species from the pick list.
REGULATORY STATUS	Click the down arrow  to select the regulatory status of the product for that particular species.
PRESCRIPTION	Click the down arrow  to select the prescription status for this particular product and species.
SUBMISSION AND APPROVAL DATES ANTICIPATED, ACTUAL	Enter the anticipated date of submission and approval, by selecting the quarter and the year from the pick list. If you know the exact date, use the field below, labeled Actual. Please see notes on how to input dates, section IIA.
COMMENTS	The comments field at the bottom of the screen corresponds to the particular species.

- The Delete button  along the top bar will delete all data in the tab page. If you click the delete button accidentally, you can undo by clicking the  button along the top bar.

D. The Presentation Tab

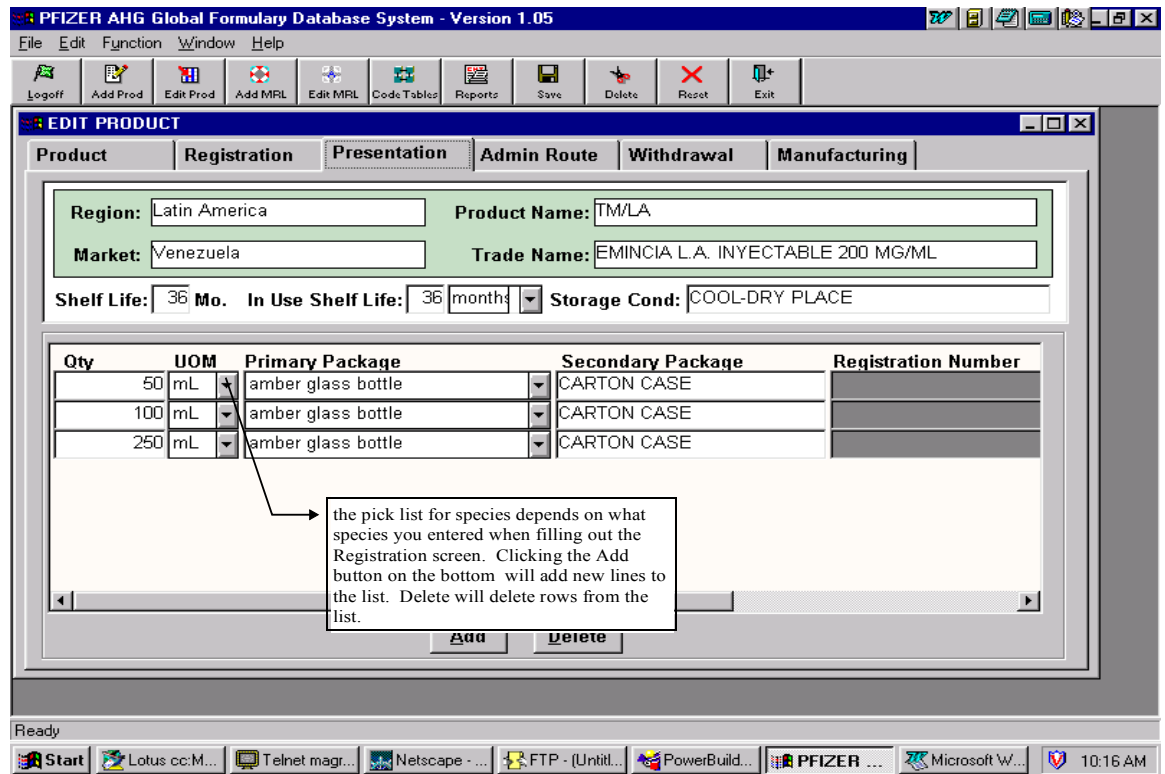


Figure 10- The Presentation Tab

Below is a list of fields in the upper and lower portions of the screen:

UPPER PORTION

**REGION, MARKET,
PRODUCT NAME
TRADE NAME**

These fields are filled in by clicking on the Product tab. They can't be modified within this screen.

**SHELF LIFE, IN-USE
SHELF LIFE AND
STORAGE
CONDITIONS**

Input information about the product's shelf life, and the storage conditions required for proper storage.

LOWER PORTION

QUANTITY/UOM

Enter the quantity of material in the package and the unit of measure.

**PRIMARY,
SECONDARY
PACKAGE**

Click the down arrow to select a primary package. Type in the secondary packaging for this product.

**REGISTRATION
NUMBER**

You may enter the registration number of each package size, if it is not species-specific (see Registration Tab).

E. Administration Route Tab

This screen allows you to input information about the administration route of the product for each species.

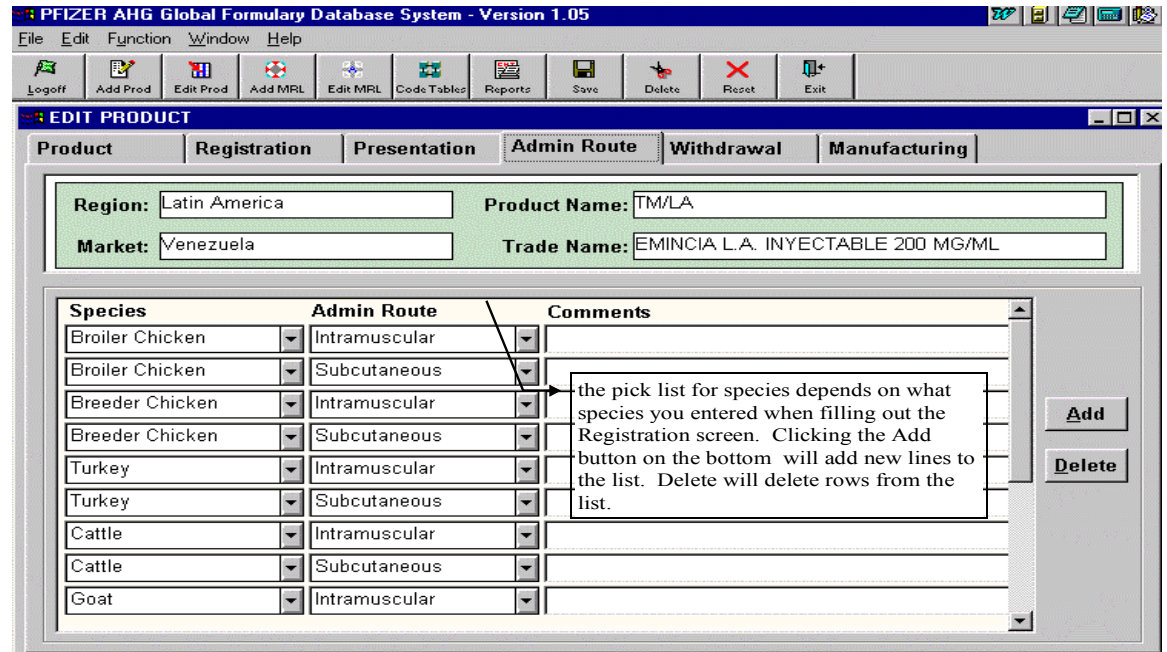


Figure 11- The Administration Route Tab


Below is a list of fields in this screen:



UPPER PORTION

REGION, MARKET, PRODUCT NAME, TRADE NAME These fields are filled in by clicking on the Product tab. They can't be modified within this screen.

LOWER PORTION

SPECIES The species for which this product is registered. The pick list here is the list of species that you inputted when filling out the Registration screen.

ADMINISTRATION ROUTE The administration route of this particular product for this particular species. Pick from the pick list by clicking the down arrow .

Click the  or  buttons to add additional species and administration route information or delete rows or records from the list.

F. Withdrawal Tab

The Withdrawal Tab is used to enter withdrawal information of the products for each species.

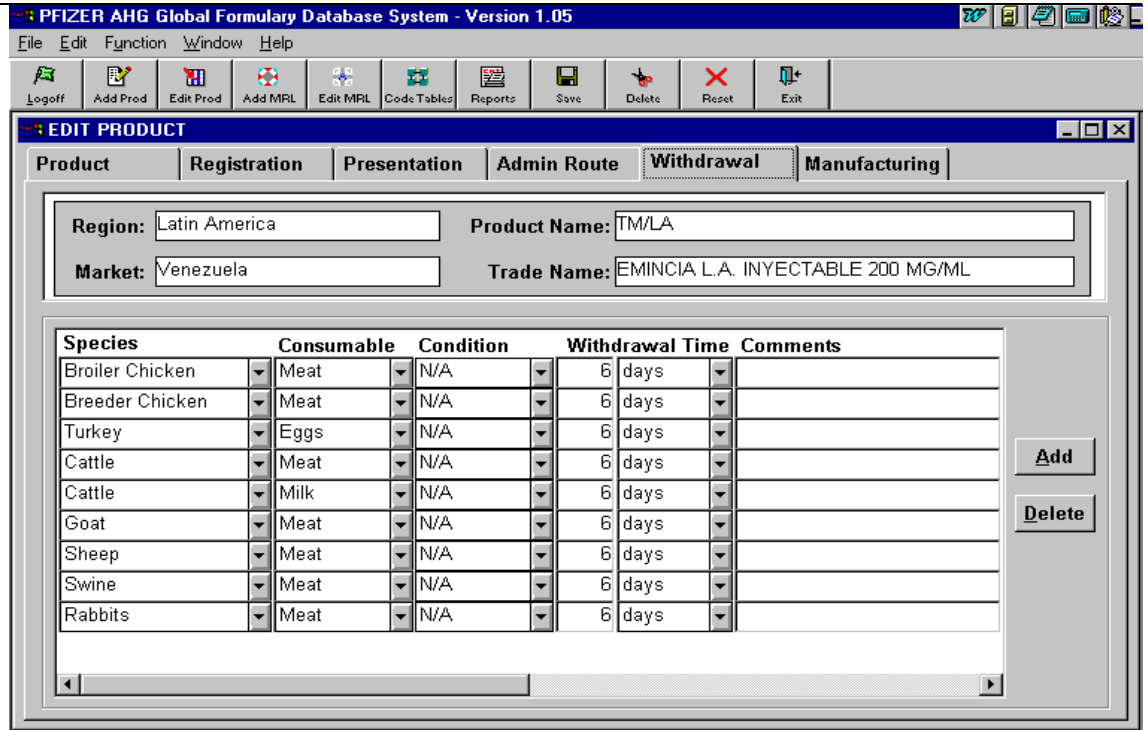


Figure 12- The Withdrawal Tab

Below is a list of fields in this screen:

UPPER PORTION

**REGION, MARKET,
PRODUCT NAME
TRADE NAME**

These fields are filled in by clicking on the Product tab. They can't be modified within this tab.


LOWER PORTION

SPECIES

The species for which this product is registered. The pick list here is the list of species that you inputted when filling out the Registration screen.

CONSUMABLE

Indicate the consumable parts of this animal (e.g. milk, eggs, meat).

Pick from the pick list by clicking the down arrow .

CONDITION



Pick the condition under which this data applies. For example, when the animal is less than 3 months.

WITHDRAWAL TIME

Input the withdrawal time.

COMMENTS

Input any comments.

Click the  or  buttons to add additional or delete records from the list.

G. Manufacturing Tab

This tab allows the user to input information about the manufacturing of this product.

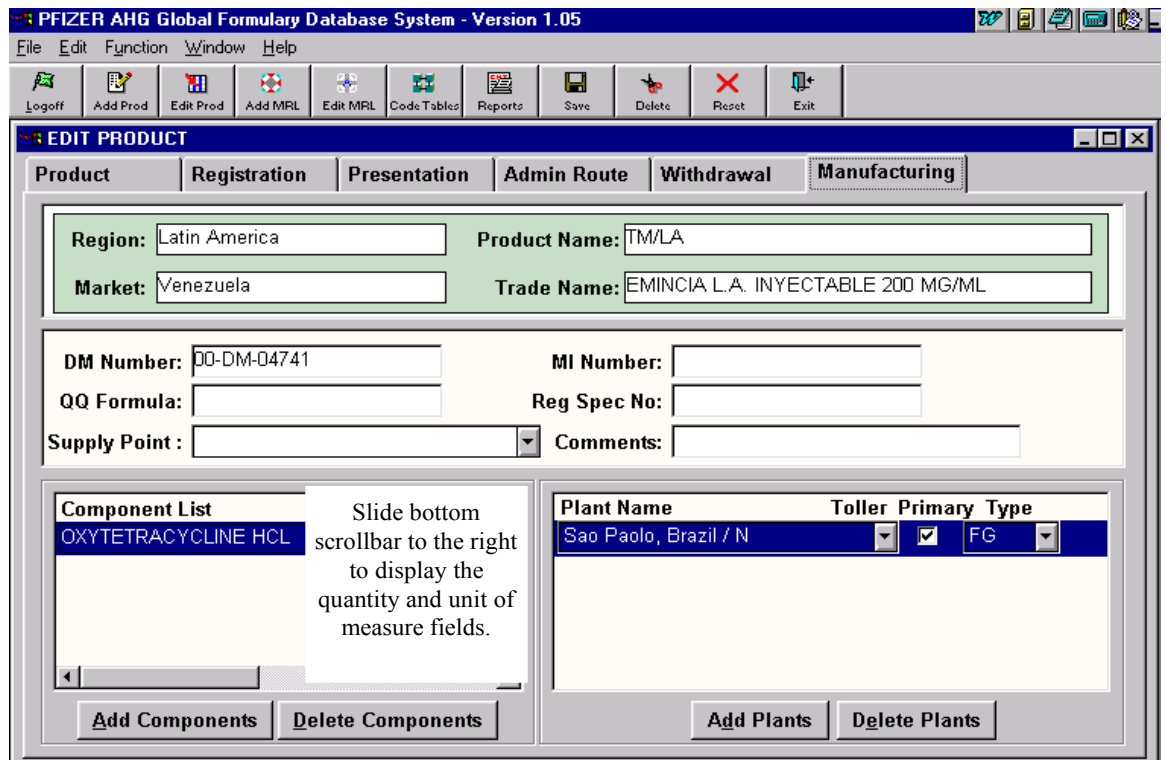



Figure 13- The Manufacturing Tab

Below is a list of fields in the upper, lower left and lower right portions of the screen:

UPPER PORTION	
REGION, MARKET, PRODUCT NAME, TRADE NAME	These fields are filled in by clicking on the Product tab. They cannot be modified within this screen.
DM NUMBER	Enter the product's DM number
MI NUMBER	Enter the product's MI Number
QQ FORMULA	Enter the product's QQ Formula
REG SPEC NO	Enter the Registration Specification Number
SUPPLY POINT	Select the product's supply point from the pick list, by pressing the down arrow  .
COMMENTS	Enter general comments about the manufacturing of this product.

LOWER LEFT

COMPONENTS WINDOW

You use this window to input the components that make up the product.

Click **Add Components** to display this subscreen:

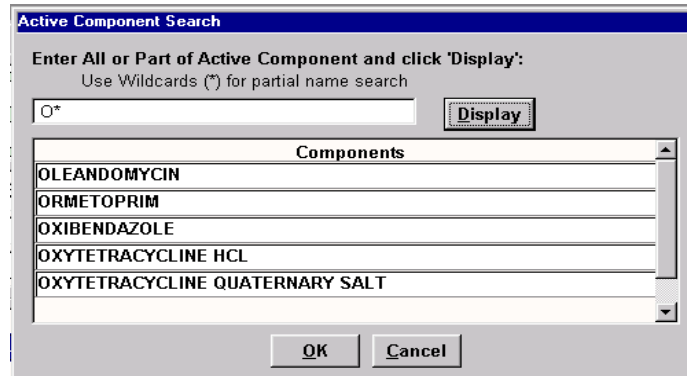


Figure 14- Active Component Search

To display a list of components, type a wildcard expression such as O* and then click

Display to display all components beginning with the letter O. Click on the component when it is displayed. It will be highlighted. Click OK to add this component to the component list. Use the same procedure to add as many components as required. Slide the bottom scrollbar to the right to display the quantity and unit of measure fields for each component.

LOWER RIGHT

ADD PLANTS AREA

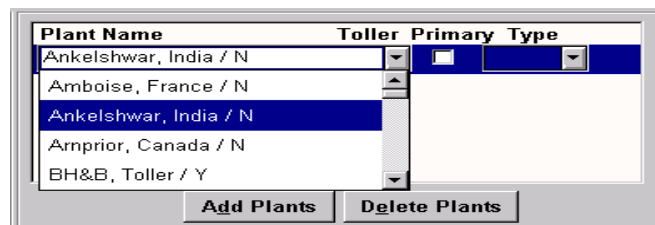


Figure 15- Add Plants Subscreen

Click Add Plants to add a plant field. Click the down arrow to activate the available list of plants. Click on the selected plant to add it to the list. The "/N" or "/Y" refers to whether this plant is a Toller.

For each plant, you may click Primary to denote it as such and you may select a type from the type list.

IV. Adding or Editing Minimum Residue Level (MRL) data





Click on the  to edit Minimum Residue Level (MRL) data. When you click Edit, you will see the following screen, that will allow you to select an item to be edited.

Figure 16- MRL Selection Screen

You must select a Region. You can then click Run Query to list all the components in that region or narrow the search by selecting a component name and/or a market. A Query Results screen will display a list of components. To select one to edit, double-click on the selection or click the



 button to select the component you want. You will then see the general screen below. A



similar screen appears directly when you click the Add  button.

Figure 17- Add MRL Screen

UPPER PORTION

REGION, MARKET

Click the down arrow  to select Region or Market data from a pick list. Note that the Market data depends on the region selected.

ACTIVE COMPONENT

To select a component, click on the  button. This will bring up a subscreen.

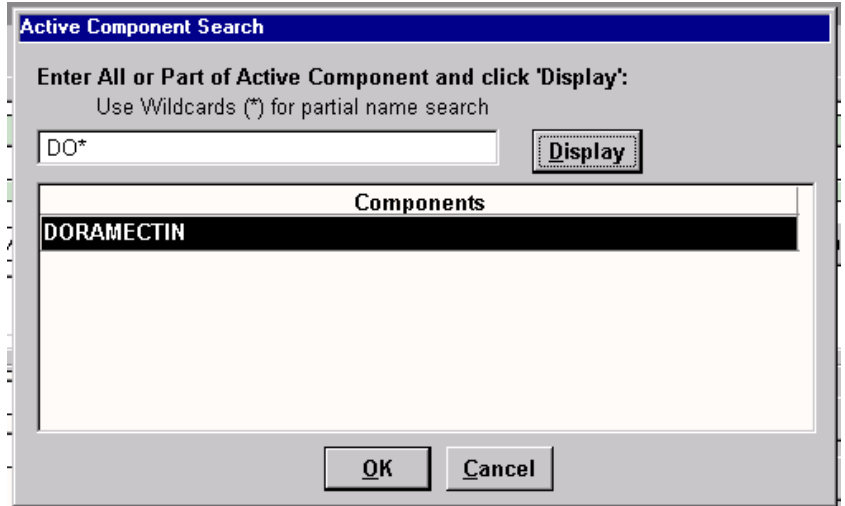


Figure 18- Active Component Search Subscreen for Add MRL screen

To find components that start with the letters DO type:

DO*

Click .

Click on one of the components to select it, then click the OK button.

COMMENTS

Enter any comments here for this particular item.

LOWER PORTION

SPECIES, TISSUE, STATUS, UOM

Click the down arrow  to select from a pick list.

You can enter more than one record by clicking the Add button.

MRL



Enter the Minimum Residue Level

DATES

Enter the Application, Approval and Expiration dates.



COMMENTS

Enter any comments here for this particular item.

Click the  or  buttons to add additional or delete records from the list.

V. Editing Code Tables

You must have administration privileges to edit the code tables.

- Click  to display the code tables editing screen.
- Click on the down arrow  on the *Select Code Table to Edit* field to display the drop down menu you see below:

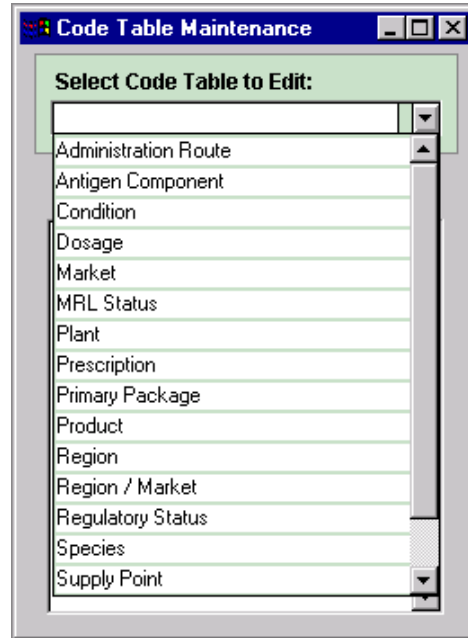






Figure 19- Code Table Maintenance

- Click on the code table you wish to edit.

- Click on  to insert items to the code table or  to delete an item. To change the contents of an item, simply type over the text.
- Alternatively you can click on the **Edit** top menu, as seen below to access the **Insert**, **Reset** and **Delete** functions.

- Click  to save the code table changes.
- Click  to reset the code table to the previous values (prior to saving).

VI. Creating Reports

A. Selecting the items that will be reported



Click on the **Reports** button to display the reports menu below:

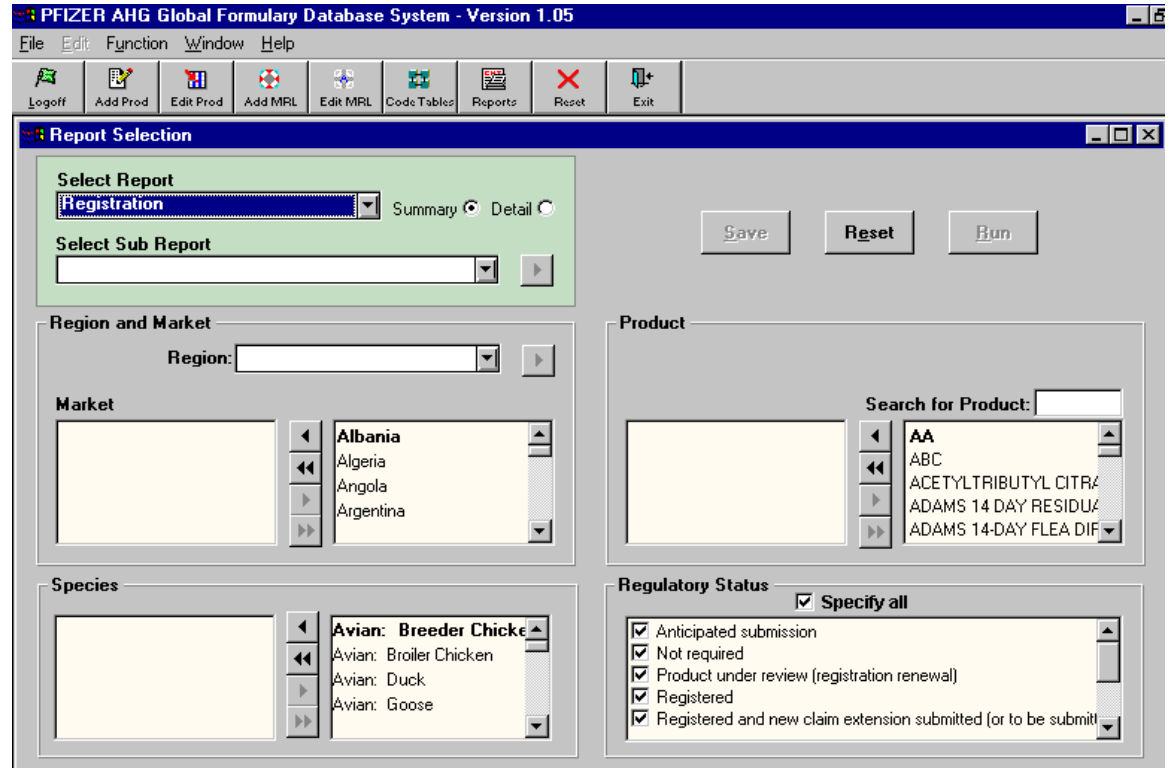

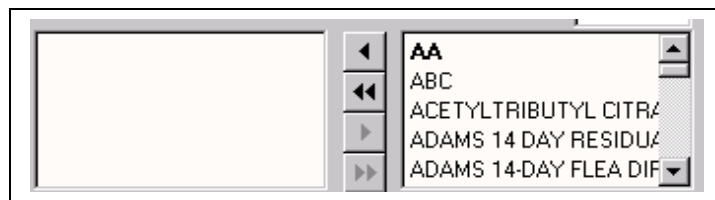




Figure 20- Report Selection Menu


Click on the down arrow  in the **select reports** field to display the list of standard reports. Click on the selected report. You may then customize the report.


For example, if you select the Registration report as shown, you will display the screen above. Note that this layout has three sets of boxes like this:



Click the  button to move selected items to the left box. The items on the left box will appear on the report.

Click the  button to move all the items to the left box.

Click the  button to remove an item from the report and move it to the right box.

Click the  button to remove all the items from the report and move them to the right box.


Note that immediately above the product box there is a search field that allows the user to select the items on the right hand side of the box by specific search criteria. Input the first few letters of the product to bring the pointer to that point on the list.




A search input field with the placeholder text "Search for Product:" and a small search icon on the right side.

In addition, the registration report has an area on the lower right that allows the user to select items by regulatory status.

B. Saving Reports

Press the  button save a report once you have configured the selected items to be reported. The system will prompt you for a report name. This name will appear on the list of subreports the next time that the reporting feature is accessed. You can then select this customized report.

Press the  button to reset the selection criteria for the report.

C. Running a report



Press the **Run** button to run and display the report.

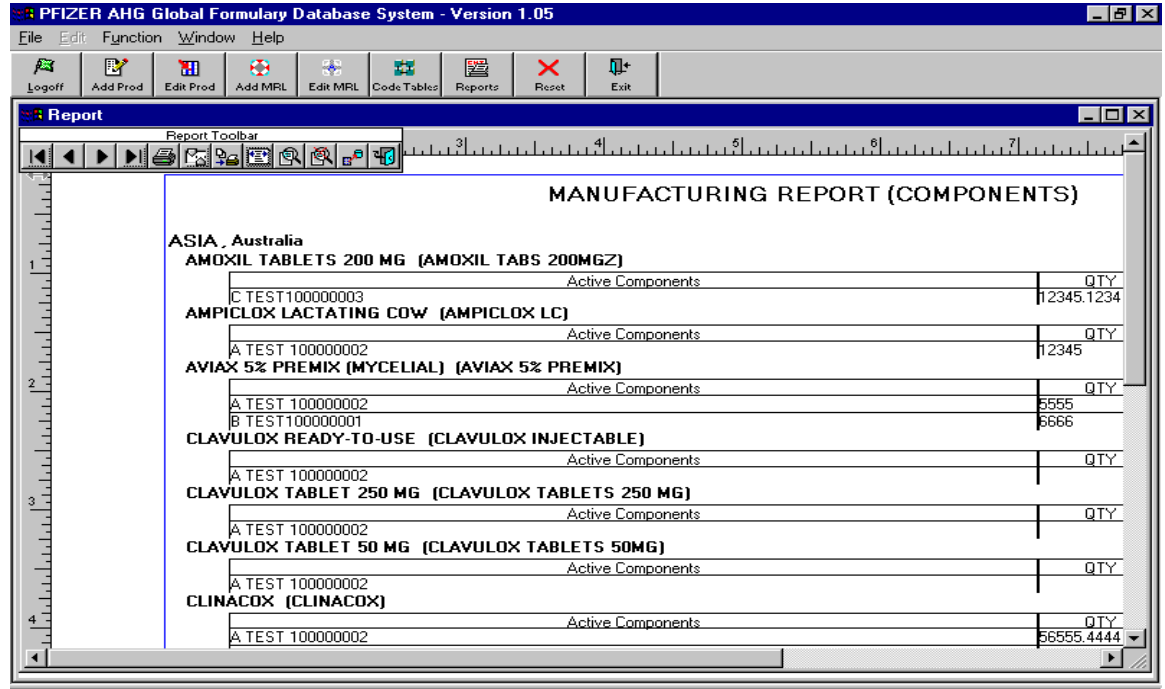


Figure 21- Report Preview

D. Format Adjustment

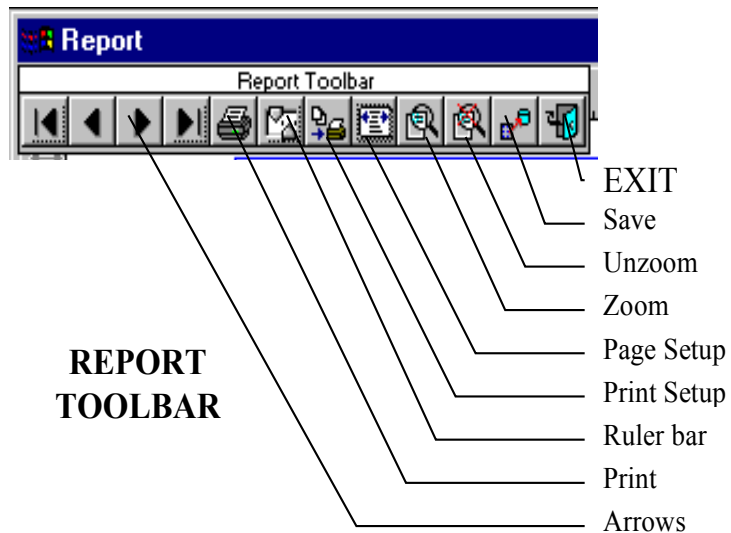


Figure 22- Report Toolbar

The above toolbar appears when previewing a report and it allows the user to adjust the format of the report.

Arrows Allow the user to page through the report.
(First, Previous, Next, Last)

To move down, you can also use the PgDown keys.

Print Sends the report to the printer

Ruler Bar Allows to view the ruler bar. Click once to view it. Click again to hide it.

Print Setup Allows you to choose and set up the printer. You can select the paper orientation, paper tray and other items.

Page Setup Allows you to set up page margins for the report.

Zoom/Unzoom Displays the report larger or smaller.

Save Saves this entire report in a different format (i.e., text, spreadsheet).

EXIT Exit the report view.

Click the Logoff button on the toolbar to logoff the system after you close the windows.