## Identification of Animal Ingredients in Dietary Supplements

#### Final Report

Contract No. 223-01-2466, TO4 Contract No. 224-96-2290, TO13

#### Prepared for

Peter J. Vardon
DHHS/Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office 2D002
5100 Paint Branch Parkway
College Park, MD 20740-3835

#### Prepared by

Sheryl C. Cates Shawn A. Karns Michaela C. Coglaiti Robin J. Anderson Heather L. Carter-Young RTI Health, Social, and Economics Research Research Triangle Park, NC 27709

RTI Project Number 08184.004

## Identification of Animal Ingredients in Dietary Supplements

**Draft Final Report** 

Contract No. 223-01-2466, TO4 Contract No. 224-96-2290, TO13

**August 15, 2002** 

Prepared for

Peter J. Vardon
DHHS/Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office 2D002
5100 Paint Branch Parkway
College Park, MD 20740-3835

Prepared by

Sheryl C. Cates Shawn A. Karns Michaela C. Coglaiti Robin J. Anderson Heather L. Carter-Young RTI Health, Social, and Economics Research Research Triangle Park, NC 27709

### Contents

1.	Introduction				
	1.1	Study Objectives	1-1		
	1.2	Overview of the DSPD-A	1-2		
	1.3	Overview of the Report	1-2		
2.	Prod	cedures for Developing the Population of Web Sites	2-1		
	2.1	1 Initial Internet Search			
	2.2	WebFerret Search	2-4		
	2.3	Buyersindex.com Search	2-4		
3.	Procedures for Searching Web Sites and Identifying Eligible Products				
	3.1	Identifying Eligible Products	3-1		
	3.2	Preventing Duplication of Products			
	3.3	Recording Web Site Information	3-5		
4.	Procedures for Coding Product Data, Data Entry, and Data Cleaning				
	4.1	Product Coding	4-1		
	4.2	Data Entry			
	4.3	Data Cleaning	4-8		
5.	Data	abase Design and Use	5-1		
	5.1	Viewing the Product Form	5-1		
		5.1.1 Information Tab	5-2		
		5.1.2 Claim Categories Tab	5-2		
		5.1.3 Ingredients Tab	5-3		

	5.2	5.2 Viewing Tables		5-4
		5.2.1	Product Table	5-5
		5.2.2	Claims Table	5-5
		5.2.3	Ingredient Table	5-5
	5.3	Search	ning by Ingredient Category	5-5
	5.4	Search	ning by Animal Type	5-6
	5.5	Search	ning by Claim Category	5-7
	5.6	Printin	g Product Records	5-8
	5.7	Viewin	g Database Objects	5-8
6.	Data	Summ	ary	6-1
	6.1	Anima	I Ingredients in the DSPD-A	6-1
	6.2	Anima	Sources for Products in the DSPD-A	6-4
	6.3	Produc	ct Claims in the DSPD-A	6-5
	Refe	erences		R-1
	App	endixes		
	Α	Appen	dix A: Web Site Worksheet	A-1
	В	Appen	dix B. Data Coding Worksheet	B-1

### **Figures**

Figure 2-1	Comparison of RTI and WebFerret Searches	2-5
-		
Figure 5-1	Example Information Tab in the Product Form	5-2
Figure 5-2	Example Claim Categories Tab in the Product Form	5-3
Figure 5-3	Example Ingredients Tab in the Product Form	5-3
Figure 5-4	Example Pop-Up Box for Animal Ingredient Information	5-4
Figure 5-5	Ingredient Category Search Screen	5-6
Figure 5-6	Animal Type Search Screen	5-7
Figure 5-7	Claim Category Search Screen	5-8
Figure 5-8	Example Product Printout	5-9

### **Tables**

Table 2-1	Results of Initial Internet Search	2-2
Table 2-2	Disposition of URLs for Initial Internet Search	2-2
Table 2-3	Disposition of URLs for WebFerret Search	2-5
Table 2-4	Disposition of URLs for Buyersindex.com Search	2-6
Table 2-5	Population of Web Sites for DSPD-A	2-6
Table 3-1	Eligible Animal Ingredients	3-2
Table 4-1	Variable Descriptions for the DSPD-A	4-2
Table 4-2	Product Coding and Data Entry Specifications	4-3
Table 4-3	Claim Categories for the DSPD-A	4-6
Table 6-1	Animal Ingredient Information in the DSPD-A	6-2
Table 6-2	Animal Ingredient Categories by Product in the DSPD-A	6-2
Table 6-3	Animal Sources by Product in the DSPD-A	6-4
Table 6-4	Claim Categories by Product in the DSPD-A	6-6

## 1 Introduction

In light of recent public health and safety concerns regarding bovine spongiform encephalopathy (BSE), efforts to prevent introduction of BSE into the United States through dietary supplements that contain animal ingredients have increased. In a letter to manufacturers and importers of dietary supplements and dietary supplement ingredients, the Food and Drug Administration (FDA) noted that serious public health risks are associated with consuming animal-derived ingredients from BSE-positive countries. Consequently, the Agency recommended that firms take precautions to ensure that their products or ingredients do not originate from countries where BSE exists (FDA, 2000). In March 2001, the National Nutritional Foods Association (NNFA) issued a guidance manual for manufacturers of bovine-derived dietary supplements outlining quality control measures they should take to ensure that BSE-contaminated products do not reach consumers (NNFA, 2001).

As part of the initiative to prevent the introduction of BSE into the United States food supply, FDA contracted with RTI to develop a Microsoft Access database of dietary supplement products sold on the Internet that contain animal ingredients. RTI started this work under Contract Number 224-96-2290, Task Order 13 and completed the work under Contract Number 223-01-2466, Task Order 4.

#### 1.1 STUDY OBJECTIVES

FDA requires information about the range of dietary supplement products that contain animal ingredients that are currently available to consumers in the United States. The objective of the

two task orders was to create a specialized database of dietary supplement products sold on the Internet that potentially contain animal ingredients. To achieve this objective, RTI developed a list of web sites that sell dietary supplement products, reviewed each web site to identify dietary supplement products that contain eligible animal ingredients, and entered information on eligible products into a Microsoft Access database. The database, referred to as the DSPD-A, is as comprehensive as possible, given the limitations of the Internet as a source of product information.

#### 1.2 OVERVIEW OF THE DSPD-A

The DSPD-A is a Microsoft Access 2000 database with 3,767 records of dietary supplement products that contain animal ingredients. The database includes information on product and brand name, web site (URL) where the product is sold, manufacturer, product form, dosage, package quantity, claims, and ingredients. For animal ingredients, information is provided on the ingredient amount, the ingredient form (processed or raw), the animal type, and country of origin, when known.

#### The DSPD-A allows users to

- Z view product information in a database form or in tables,
- Z query products by animal ingredient category (e.g., enzyme or liver),
- Z query products by type of animal from which the animal ingredient is derived, and
- Z query products by claim category.

#### 1.3 OVERVIEW OF THE REPORT

This report is organized as follows. Section 2 describes the procedures we used to develop a list of web sites that sell dietary supplement products (i.e., the population). Section 3 describes the procedures we used to search each web site in the population and identify dietary supplement products that contain animal ingredients for inclusion in the database. Section 4 describes the procedures we used to code the product data for data entry and our procedures for data cleaning. Section 5 describes the design of the DSPD-A and provides instructions for using the database. Section 6

summarizes the product and ingredient information contained in the DSPD-A.

# Procedures for Developing the Population of Web Sites

This section describes the procedures we used to develop a list of web sites that sell dietary supplement products on the Internet. This list served as the population of web sites for the DSPD-A. We initially conducted an Internet search using multiple search engines that yielded nearly 1,200 unique URLs or web sites. We then augmented this search using WebFerret and buyersindex.com. The final population includes 1,667 web sites.

#### 2.1 INITIAL INTERNET SEARCH

We used multiple search engines to develop the population, including the following:

- Z Excite
- Z Fast
- Z Google
- Z HotBot
- Z Lycos

We used the following criteria for conducting each Internet search:

- Z Must contain the words "dietary supplement" and "secure" (as a proxy for sites that sell products online).
- Z Limit the search to North American dot-com sites.
- Z Limit the search to English language sites.
- Z Offensive content reduction "off."

As shown in Table 2-1, the searches using the five search engines yielded more than 33,700 URLs that met our search criteria. However, the current search engine technology prevents the user from retrieving all of the URLs identified in the search. Thus, we were only able to retrieve 7,624 of these URLs. We downloaded the list of retrievable URLs from each search engine into Excel. We then eliminated URLs that were duplicates (i.e., had the same URL or were URLs for the same dot-com site). After purging the list of duplicates, 2,045 URLs remained.

Table 2-1. Results of Initial Internet Search

	Number of URLs Meeting Search Criteria	Number of Retrievable URLs
Excite	3,013	1,000
Fast	6,894	4,000
Google	8,516	486
HotBot	8,300	1,000
Lycos	7,012	1,138
Total	33,735	7,624

We visited each of the 2,045 URLs to determine if the web site was eligible for inclusion in the population. Table 2-2 shows the disposition of each of the 2,045 URLs.

Table 2-2. Disposition of URLs for Initial Internet Search

Disposition	Number	Percentage of Total
Ineligible	638	31%
Duplicate (i.e., not a unique site)	485	24%
Not accessible	149	7%
Eligible	773	38%
Total	2,045	100%

A web site was considered eligible for inclusion in the population if it sells dietary supplement products. For the purposes of this study, we used the Dietary Supplement Health and Education Act

(DSHEA) definition of dietary supplements. According to this definition, dietary supplements include vitamins, minerals, herbals and botanicals, herbal and botanical extracts, animal extracts, amino acids, proteins, concentrates, metabolites and constituents, teas (if dietary supplements are an ingredient), and other miscellaneous products. Dietary supplements by definition must be taken orally. They come in many dosage forms, including pills, liquids, powders, or granules. They do not include food products or products intended to replace a meal. Homeopathic remedies and Eastern medicines (Ayurvedic medicines from India and Chinese traditional medicines) are not dietary supplements; however, if the product was labeled as a "supplement," for the purposes of this study it was considered eligible for inclusion in the population.

Nearly one-third of the sites were ineligible because they do not sell dietary supplement products (e.g., information-only site or site with a list of links) or sell products other than dietary supplements (e.g., homeopathic remedies, cosmetics, or products intended for animal consumption). About 150 of the ineligible URLs were for "link" sites that provided lists of URLs to which the user could link. We reviewed the list of links to determine if any of the sites identified were eligible for inclusion in the population and not already found in our initial search; if so, the URL was added to the population. This resulted in 409 web sites being added to the population.

Because of the "linking" capabilities of the Internet, there is the opportunity for many different types of marketing arrangements between distributors and manufacturers. We carefully examined each web site to determine if it was a unique site. Web sites for independent distributors were considered eligible for inclusion in the population if products can be purchased from that site (e.g., Metabolife or Herbalife). Web sites for independent distributors that linked to a manufacturer or another distributor web site (that was already in the population) to purchase products (e.g., Freelife) were considered duplicates. URLs that linked (either automatically or by the user) to another web site already in the population were also considered duplicates. We found many instances where the same web site can be accessed from

different URLs. Nearly one-fourth of the URLs were duplicates and thus ineligible for inclusion in the population.

Seven percent of the URLs were not accessible. We tried to access each of these URLs at least two times on two different days before assigning a disposition of not accessible.

A total of 773 URLs (38 percent) linked to unique, eligible web sites. The results of our initial search (n=773), augmented with our review of the "link" sites (n=409), yielded 1,182 web sites that sell dietary supplement products.

#### 2.2 WEBFERRET SEARCH

WebFerret (published by FerretSoft) allows users to search multiple search engines at one time. For the WebFerret search we used the same search criteria that we used for the initial Internet search with the exception that we did not limit the search to North American dot-com sites. The WebFerret search resulted in 2,269 URLs after purging the list of duplicates. We compared the list generated by the WebFerret search to the list generated by the initial search described in Section 2.1 (referred to as the RTI list). For the RTI list we used the 2,045 URLs from the original list (which includes ineligible URLS), plus the 409 URLs added from the link sites, and 64 new URLs added during the product searching process (n=2,518). The results of the comparison are illustrated in Figure 2-1. Of the 2,269 URLs in the WebFerret list, 596 matched those in the RTI list and 1,673 did not match (i.e., are not in the RTI list). Of the 2,518 URLs in the RTI list, 1,922 did not match the WebFerret list, thus both search methods yielded unique URLs.

We visited each of the 1,673 URLs to determine if the web site was eligible for inclusion in the population. Table 2-3 shows the disposition of each of the 1,673 URLs. The WebFerret search yielded 228 eligible URLs for inclusion in the population.

#### 2.3 BUYERSINDEX.COM SEARCH

The web site, buyersindex.com, allows users to search 20,000 Web shopping sites and mail order catalogs. For the buyersindex.com search, we used the following search criteria:

Z Must contain the words "dietary supplement."

Z Limit the search to web catalogs, directory or search engines, and web pages.

Figure 2-1. Comparison of RTI and WebFerret Searches

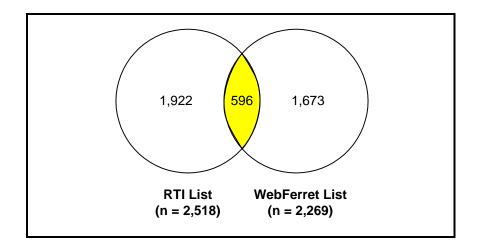


Table 2-3. Disposition of URLs for WebFerret Search

Disposition	Number	Percentage of Total
Ineligible	1,099	65%
Duplicate (i.e., not a unique site)	79	5%
Not accessible	267	16%
Eligible	228	14%
Total	1,673	100%

- Z Limit the search to retail sites.
- Z Limit the search to sites that ship to the United States.

The buyersindex.com search resulted in 204 URLs. We compared the list generated by the buyersindex.com search to the list generated by the initial search (referred to as the RTI list) and the WebFerret search. Of the 204 URLs in the buyersindex.com list, 136 did not match the RTI or WebFerret lists.

We visited each of the 136 URLs to determine if the web site was eligible for inclusion in the population. Table 2-4 shows the disposition of each of the 136 URLs. The buyers index.com search yielded 68 eligible URLs for inclusion in the population.

Table 2-5 shows the population of web sites for the DSPD-A. A total of 1,667 web sites are included in the population. While we believe that the population is as comprehensive as possible given

Table 2-4. Disposition of URLs for Buyersindex.com Search

Disposition	Number	Percentage of Total
Ineligible	58	43%
Duplicate (i.e., not a unique site)	0	0%
Not accessible	10	7%
Eligible	68	50%
Total	136	100%

Table 2-5. Population of Web Sites for DSPD-A

Search	Number
Initial Internet search	1,182
WebFerret	228
Buyersindex.com	68
Brand name web sites added during review process <sup>a</sup>	189
Total	1,667

<sup>&</sup>lt;sup>a</sup>As described in Section 3, we added brand name web sites that were not included in the population to facilitate the web site searching process and to help prevent the inclusion of duplicate products in the database.

the limitations of the search engine technology, it is likely that some eligible web sites were excluded from the population. It is difficult to estimate, however, how many sites were excluded. As previously discussed, our review of the "link" sites yielded 409 additional sites, so some web sites were excluded from our initial search. Most of these sites were smaller sites (i.e., sell only a few products); however, some larger sites were missed. Augmenting our initial Internet search with the WebFerret and buyersindex.com searches, our review of the "link" sites, and brand name web sites (as described in Section 3) helped to increase the comprehensive of the population.

# Procedures for Searching Web Sites and Identifying Eligible Products

In this section, we describe the procedures used to search each eligible web site and identify dietary supplement products containing eligible animal ingredients for inclusion in the DSPD-A.

#### 3.1 IDENTIFYING ELIGIBLE PRODUCTS

We searched each web site in the population to identify dietary supplement products that contain eligible animal ingredients. We did not search web sites that require membership for access. Also, some web sites included in the population were no longer active and could not be accessed.

Table 3-1 provides the list of eligible animal ingredients developed by RTI in collaboration with FDA. This list served as a guide during the searching process and is not exhaustive. Additional eligible animal ingredients were identified during the searching process and included in the DSPD-A.

Based on discussions with FDA, we excluded the following ingredients from the list of eligible animal ingredients because they are, in most cases, synthetically derived or of very little risk of BSE contamination:

Table 3-1. Eligible Animal Ingredients

Acetate Embryo Adrenal Emu oil Alaninea Enzymes<sup>b</sup> **Albumin** Estradiol<sup>b</sup> Allantoin Eye

Fatty acids<sup>b</sup> Amino acidsa **Fetus** Amylase<sup>b</sup> Antler Garum Aorta Gelatinc Gland Arachidic<sup>b</sup>

Arachidonic<sup>b</sup> Glutamic acida Arginine<sup>a</sup> Glutamine<sup>a</sup> Asparagine<sup>a</sup> Glycerine<sup>b</sup> Glycinea Aspartic acida Behenic<sup>b</sup> Glycogenb Bile Glycolipids<sup>b</sup> Blood Heart Bone Histidine<sup>a</sup> Brain Hormones<sup>b</sup> Calfskin extract Hyaluronic acidb Hypothalamus

Cartilage lleum

Castor Immunoglobulin Ceroticb Isoleucine<sup>a</sup> Cetyl myristoleateb Kidney Chondroitin sulfate Lauricb Collagen Leucinea Colon Lignoceric<sup>b</sup> Corticosteroid Linoleic<sup>b</sup> Cortisone Lipaseb Creatine Liver Lung Cysteinea

**DNA**<sup>a</sup> Lymph nodes Duodenum Lysinea Dura mater Maltoseb

(continued)

Table 3-1. Eligible Animal Ingredients (continued)

Mammary Pizzle

Capricb

Marrow Placenta

Melatonin Pregnenolone<sup>b</sup>

Methionine<sup>a</sup> Proline<sup>a</sup>
Microcrystalline hydroxyapatite (MCHC) Prostate
Mucin Rennet
Muscle extract Rennin
Musk RNA<sup>a</sup>
Myelin Serine<sup>a</sup>

Myristic<sup>b</sup> Sphingolipids<sup>b</sup>
Nasal mucosa Sphingomyelin
Oleic/oleic acid<sup>b</sup> Spinal cord
Oophorinium Spleen

Orchic/orchitnum Stearic acidb Stomach **Ornithine**<sup>a</sup> Ovary **Testes** Ox bile Testicular **Thalamus** Palmitic<sup>b</sup> Palmitoleic<sup>b</sup> Theronine<sup>a</sup> **Pancreas Thymus** Pancreatin **Thyroid** Panthenol Thyroidinum Parathyroid Tonsil

Pepsin<sup>b</sup> Trachea
Peripheral nerves Triglyceride oil
Phenylalanine<sup>a</sup> Tryptophan<sup>a</sup>

Phosphatides<sup>b</sup> Tuberculostearic<sup>b</sup>

Phosphatidic acid<sup>b</sup> Tyrosine<sup>a</sup>
Phosphatidylserine<sup>b</sup> Urea
Pigskin extract Uterus
Pineal gland Valine<sup>a</sup>

**Pituitary** 

- Z androstendione and related compounds
- Z choline
- Z co-enzyme Q-10

<sup>&</sup>lt;sup>a</sup>Eligible ingredient if from animal-derived sources.

<sup>&</sup>lt;sup>b</sup>Eligible ingredient unless the web site described the product or ingredient as from nonanimal sources.

<sup>&</sup>lt;sup>C</sup>Dietary supplement products that contain gelatin as an *active* ingredient are eligible for inclusion in the database. Gelatin used to make capsules is considered inactive.

- Z colostrum
- Z dehydroepiandrosterone (DHEA)
- Z dimethylaminoethanol (DMAE)
- Z egg (e.g., yolk, albumen)
- Z lecithin
- Z milk products (e.g., lactose, lactoferrin, whey)
- Z taurine

A product was considered eligible for inclusion in the DSPD-A if it met *all* of the following criteria:

- Z The product is a "dietary supplement" as defined in Section 2:
- Z The product contains at least one eligible animal ingredient as identified in Table 3-1; *and*
- Z The eligible animal ingredient is described on the web site as "active." If "active" was not specified, we assumed the ingredient was active and the product was considered eligible. An exception to this rule was animal glands and tissues. These ingredients were always considered eligible regardless of whether they are active or inactive.

A product was considered ineligible for inclusion in the DSPD-A if *any* of the following criteria applied:

- Z The product did not meet the definition of a "dietary supplement" as defined in Section 2;
- Z The product did not contain an eligible animal ingredient as identified in Table 3-1:
- Z The web site described the product or its ingredients as derived from animal sources, suitable for vegetarians, or synthetic; or
- Z The product contains an eligible animal ingredient but it is described on the web site as "inactive," "excipient," or "other." An exception to this rule was animal glands and tissues. These ingredients were always considered eligible regardless of whether they are active or inactive.

Certain ingredients required special consideration to determine if they were eligible. The following ingredients were considered eligible *unless* the product description described the product or the ingredient as being synthetically derived or from a non-animal source(s):

- Z enzymes (e.g., amalyase, lipase, protease)
- Z fatty acids (e.g., linoleic acid, oleic acid)
- Z hormones (e.g., hGH, IGF-1)

Amino acids (e.g., alanine, glutamic acid, lysine) were considered ineligible *unless* the product description described the product or the ingredient as being derived from an animal source(s).

#### 3.2 PREVENTING DUPLICATION OF PRODUCTS

We used the procedures described below to help prevent the inclusion of duplicate products in the database. Because of human error, some duplication was unavoidable during product review. However, we attempted to combine any duplicate product information at the data cleaning stage.

Many web sites sell more than one brand of dietary supplement product (i.e., retailer web sites). For example, some web sites specialize in dietary supplements for bodybuilding and fitness purposes and sell many different brands of products. When reviewing a web site that sells more than one brand, we went through the following process for each brand sold on the web site:

- We checked the population of web sites to determine if the brand had its own web site that was already included in the population. If so, we did not review that brand's products on the retailer web site, instead these products were reviewed when reviewing that brand's web site. We found that the brand's own web site generally provides the most complete product information available.
- If the brand's web site was not included in the population we did an Internet search to determine if the brand had its own web site. If so, we added that web site to the population and did not review that brand's products on the retailer web site (these products would be reviewed later when reviewing that brand's web site).
- If the brand did not appear to have its own web site, products of that brand name were reviewed at the retailer's web site. Any duplicate products were then purged at the data cleaning stage.

We recorded the brands that are sold on retailer web sites for which the product information was obtained from the brand web site. We compiled this information into a notebook that was provided to FDA.

#### 3.3 RECORDING WEB SITE INFORMATION

Once we determined a web site sold products eligible for inclusion in the DSPD-A, we printed the home page for the web site and all available information on each eligible product. In addition, we recorded specific information about each eligible product on the Web Site Worksheet (See Appendix A.) Information recorded on the Web Site Worksheet included the following:

- Z Reviewer's name
- Z Date
- Z Web site URL
- Z Retailer name
- Z Brand name of each eligible product
- Z Product name of each eligible product
- Z Total number of eligible dietary supplement products

## 4

# Procedures for Coding Product Data, Data Entry, and Data Cleaning

This section describes the procedures we used to code the information on the dietary supplement products for data entry and our data cleaning procedures following data entry.

#### 4.1 PRODUCT CODING

Table 4-1 provides a brief description of each variable included in the DSPD-A and its format. The DSPD-A includes the following information: brand and product name, manufacturer, URL, product form (e.g., liquid or tablet), information on recommended dosage, quantity, price, types of claims, and ingredients. In addition, the database includes the following variables specifically for animal ingredients: product serving size, ingredient amount per serving, form (processed or raw), type of animal (e.g., bovine or porcine), animal category (e.g., mammal or fish), and country of origin.

Using the product information printed from the web site, we completed a Product Coding Form for each product. Appendix B provides a copy of the 2-page Product Coding Form. Page 1 of the form was used to record product information. Page 2 of the form was used to record information on each animal ingredient contained in the product. If the product contained more than four animal ingredients, then additional copies of Page 2 were

completed. Table 4-2 describes the procedures we used to code the

Table 4-1. Variable Descriptions for the DSPD-A

Variable Name	Format	Description
		Product Identification
Product ID	Autonumber	Record number automatically entered by Microsoft Access
Date Entered	Date/time	Date the record was entered into the database
Product Name	Text	Name of the product
Brand Name	Text	Brand name of the product
Manufacturer	Text	Name of the manufacturer
URL	Text	URL or web site where product is sold
		Information on Dosage
Product Form	Text	Dosage form of the product (e.g., capsule, tablet, powder)
Daily Dose Measure	Text	Unit of measure for daily dose (e.g., capsule, scoop, teaspoon)
Assigned Daily Dose	Number	Number of doses recommended per day
Daily Dose Comments	Text	Description of daily dose
	Ir	nformation on Package Quantity
Number of Units	Number	Units per package
Unit of Measure	Text	How product quantity is measured (e.g., capsules, ounces, milligrams)
Price	Currency	Price of the product for the given quantity
		Information on Claims
Claim Category	Text	Specific claims by category (e.g., allergies, digestive, weight loss)
		Information on Ingredients
Ingredient Order	Number	Numeric order of the ingredient in the list of ingredients
Ingredient 1- Ingredient 30	Text	First 30 ingredients entered as they appear on the web site
Ingredient Type	Text	Animal-active, ineligible-active, or inactive
	In	formation on Animal Ingredients
Serving Size	Number	Unit of daily dose for animal ingredient amount
Daily Dose Measure <sup>a</sup>	Text	Unit of measure for daily dose (e.g., capsule, scoop, teaspoon)
Ingredient Amount	Number	Amount of animal ingredient per serving
Unit of Measure	Text	Unit of measure for animal ingredient amount (e.g., milligram, gram)
Ingredient Form	Text	Form of ingredient (processed or raw)
Animal	Text	Animal from which ingredient is derived (e.g., bovine, cervine)

Variable Name	Format	Description
Animal Category	Text	Category of animal from which ingredient is derived (mammal, bird, fish, amphibian, reptile, other, unknown)
Country	Text	Country of origin
Ingredient Category	Text	Ingredient category assigned by RTI (e.g., liver, brain, amino acid)

<sup>&</sup>lt;sup>a</sup>The same information is displayed in both the Product and Animal Ingredient database tables.

Table 4-2. Product Coding and Data Entry Specifications

Product Identification  Record number automatically entered by Microsoft Access.  Date the record was entered into the database; automatically entered by Microsoft			
Date the record was entered into the database; automatically entered by Microsoft			
Access.			
Enter name of the product as it appears on the web site.			
Enter brand name of the product as it appears on the web site. Enter "unknown" if not available.			
Enter manufacturer of the product if provided on the web site. Enter "unknown not available.			
Enter URL or web site where product is sold (xxxxxxxx.com).			
Information on Dosage			
Enter dosage form of the product (e.g., capsule, tablet, powder). Enter "unknow if not available.			
Enter unit of measure for daily dose (e.g., capsule, scoop, teaspoon). Enter "unknown" if not available.			
Enter the total amount of the product that is recommended to be taken in one day as specified on the web site. If a range of daily doses is specified, the Assigned Daily Dose is the <i>maximum</i> daily dose. For example, if the product information states, "take 1 to 3 tablets twice a day," then the product's Assigned Daily Dose 6. Field has null value if not available.			
If the Assigned Daily Dose cannot be determined or needs further clarification, record that information in this field. For example, statements such as, "Take 2 to 4 capsules before each meal" and "Persons weighing 150 pounds or less: 2 scoops, Persons weighing 150 pounds or more: 3 scoops" are recorded in this field.			

#### **Information on Package Quantity**

If the product is offered in different quantities, enter this information for each package quantity.

Variable Name	Specifications				
Number of Units	Enter the number of units in package. Field has null value if not available.				
Unit of Measure	Enter how the product is measured (e.g., capsules, ounces, milligrams). Enter "unknown" if not available.				
Price	Enter the price of the product rounded to the nearest whole dollar. The regular price is reflected. Sale prices and specials, such as "buy one get one free" are not recorded. Field has null value if not available.				
	Information on Claims				
Claim Category	Review claims made about the product and select the claims that apply. Table 4-3 provides the list of claims and a description. Field has null value if no claims made about product.				
	(continued)				

Table 4-2. Product Coding and Data Entry Specifications (continued)

Variable Name	Specifications						
Information on Ingredients							
Ingredient Order	Enter the numeric order of the ingredient in the list of ingredients.						
Ingredient 1- Ingredient 30	Product coders highlight the first 30 ingredients on the product printout. If more than 30 ingredients are listed, only the first 30 ingredients, beginning with active ingredients, are recorded. If animal ingredients appear after the first 30 listed ingredients, skip one or more ineligible ingredients to ensure the animal ingredients are included in the DSPD-A.						
	Data entry enters the ingredient name exactly as it appears on the web site, and in the order in which they appear on the web site.						
Ingredient Type	For each ingredient, indicate ingredient type: animal-active, ineligible-active <sup>a</sup> , or inactive.						
Information on Animal Ingredients  Enter this information for each eligible animal ingredient. If no animal ingredient information is available, data entry checks the "No Ingredient Information" box <sup>b</sup> .							
Serving Size	Enter unit of daily dose for animal ingredient amount. Field has null value if not available.						
Daily Dose Measure	Previously coded/entered; also displayed with animal ingredient information.						
Ingredient Amount	Enter the amount of the animal ingredient per serving. Field has null value if not available.						
Unit of Measure	Enter the unit of measure for the animal ingredient amount (e.g., milligram, granounce). Enter "unknown" if not available.						
Ingredient Form	Enter the form of the animal ingredient (processed or raw). Enter "raw" if the animal ingredient is described as "raw" or "lyophilized," otherwise, enter "processed."						
Animal	Enter the animal from which the animal ingredient is derived (e.g., bovine, cervin porcine). Enter "unknown" if not available.						
Animal Category	Enter the category of animal from which the animal ingredient is derived (mamma bird, fish, amphibian, reptile, other). Enter "unknown" if not available.						
Country	Enter the country of origin for the animal ingredient. Enter "unknown" if not available.						
Ingredient Category	Ingredient category assigned by RTI after data entry (see Data Cleaning Section).						

aIneligible-active ingredients includes animal ingredients that are not eligible for inclusion in the database (e.g., whey and egg products) and non-animal ingredients.
 bIf the "No Ingredient Information" box is checked: numeric fields have null values, the ingredient form is "processed," and all other text fields are "unknown."

product and animal ingredient information for data entry. Table 4-3 provides a list of the product claim categories included in the database and a description of each claim.

Table 4-3. Claim Categories for the DSPD-A

Claim Category	Description			
Allergies	Allergies, hay fever			
Anti-Aging	Aging			
Antioxidant	Free radical damage, cancer risk			
Arthritis/Joint Pain	Arthritis, joints			
Bones/Skeleton	Osteoporosis, bones; NOT arthritis or joints			
Calcium/Osteoporosis <sup>a</sup>	Calcium and prevention of osteoporosis are linked			
Circulatory	Heart, cardiovascular, blood, blood pressure, circulation, cholesterol, blood sugar, varicose veins, diuretic effects			
Digestive	Laxative, cleansing effect, digestion, stomach, ulcers, reflux, parasite control, hemorrhoids, removal of toxins			
Endocrine System	Endocrine system, includes: hypothalamus, pituitary, thyroid, parathyroid, adrenal, pineal, reproductive glands (ovaries, testes); pancreas; hormones			
Energy Alertness	Energy level, mental alertness, memory, attention, ability to concentrate			
Female Health	Female reproductive system, menstrual cycle, menopause, Premenstrual Syndrome, breast enhancement			
Fiber/Heart Disease <sup>a</sup>	Soluble fiber from whole oats or psyllium husks and prevention of coronary heart disease are linked			
Fitness/Bodybuilding	Building muscle; gaining weight; improving fitness, endurance, stamina, exercise			
Folic Acid/Birth Defects <sup>a</sup>	Folic acid or folate and prevention of neural tube birth defects are linked			
Immune System	Immune system, colds, flu, other types of infections			
Mental Health	Depression, anxiety, mood, relaxation, sleep, overall feeling of well-being, stress			
Other	Other claims not elsewhere included			
Other Organs	Other organs not elsewhere included, such as liver, gall bladder, eyes, ears			
Pain Relief	Pain, discomfort			
Respiratory	Asthma, breathing, snoring, bad breath, sinuses			
Sexual Function	Sex drive, performance			
Skin, Hair, Nails, Teeth	Skin, hair, nails, teeth			
Supplementation	Increases in dietary intake, nutrients not obtained in foods			
Urinary Tract	Urinary tract, bladder, prostate, kidney			
Weight Loss	Weight loss, appetite control, metabolism			

<sup>&</sup>lt;sup>a</sup>These claims were only selected if a claim relates the ingredient to the stated condition. FDA-allowable claims link: calcium and prevention of osteoporosis; soluble fiber and prevention of coronary heart disease; and folic acid or folate and prevention of neural tube birth defects.

If the same product is available in different formulations (e.g., tablets and capsules) or different potencies (e.g., 50 mg and 100 mg) each product was considered a unique product and a separate Product Coding Form was completed. If the same product is available in different quantities (e.g., 100 and 200 tables) only one Product Coding Form was completed and the information on different quantities (number of units and price) was recorded on the form. If the same product is available in different flavors (e.g., chocolate and vanilla), one Product Coding Form was completed for one flavor (randomly selected).

Some manufacturers package several dietary supplement products together in a pack (e.g., hydroxycut and creatine) and sell them as one "product." If the individual components of the pack are sold separately on the web site, then each component was considered a unique product and a separate Product Coding Form was completed. If the individual components are not sold separately on the web site, then the product information was not included in the data base because the database is not structured to record information on product packs.

We attached the completed Product Coding Form to the web site product information and compiled them into notebooks. A total of 92 notebooks were delivered to FDA as part of the final project deliverable.

#### 4.2 DATA ENTRY

RTI subcontracted with a professional data entry firm to enter the product and ingredient information into the Access database. Trained data entry clerks keyed the information from the completed Product Coding Forms and the product printouts (i.e., the list of ingredients) into the database.

For quality assurance purposes, we randomly selected a sample of 25 percent of the products entered in the database to verify that the data were entered correctly. Any coding or data entry mistakes that we found were corrected in the database.

#### 4.3 DATA CLEANING

After data entry, we cleaned the data, including consolidating any duplicate products. Our data cleaning procedures are described below.

- 1. For each variable in the database (with the exception of Product Name and Daily Dose Comments), we printed the list of entries and reviewed the entries for any typographical errors. For the Product Form, Daily Dose Measure, and Package Quantity Unit of Measure fields, we consolidated entries where appropriate (e.g., "spray" and "mouth spray" were combined into "spray"). For the ingredient names, we only corrected obvious typographical errors made during data entry so that the ingredient names are entered exactly as they appear on the web site. For many ingredients, there is more than one acceptable spelling (e.g., ashwaganda extract and ashwagandha extract) so no corrections were made.
- To correct any product coding or data entry errors, we performed several checks on the database. For example, we conducted checks using queries to ensure that any ingredients with "bovine" in the product name were coded as "bovine" for the Animal field and "mammal" for the Animal Category field.
- 3. We created a new variable, Ingredient Category, to classify ingredients by organ/tissue source or type (e.g., fatty acid or enzyme). For example, the ingredient category for liver concentrate, liver, liver extract, and liver substance is "Liver," and the ingredient category for amylase, lipase, protease, and digestive enzymes is "Enzymes."
- 4. We printed records that have the same product name and brand name (i.e., duplicates). We reviewed the product information entered for each set of duplicates and retained the product record with the most complete product information and deleted the duplicate record(s). When appropriate, we consolidated product information so that the retained product record provides the most complete product information available. (Only one URL is reported in the database.) Despite extensive efforts to purge the database of duplicates, it is likely that some duplicates remain. For many products, the active ingredient is the product name (e.g., creatine or melatonin) and the brand name is not provided on the web site, so it is difficult to identify duplicates. Also, multiple spellings of the same product name make it difficult to identify duplicates. Finally, it is possible for the same product to be sold under multiple brand names. We deleted approximately 700 duplicate records from the database.

5. We deleted any record in any table that is not used in the database; for example, for the country of origin variable we only retained records with countries used in the database.

The final, clean dataset includes 3,767 product records, with 6,374 animal ingredient records.

## Database Design and Use

The DSPD-A is a Microsoft Access 2000 database that opens to a main menu. From the main menu of the DSPD-A, a user can do the following:

- Z Open the Product Form
- Z Open the Product Table
- Z Open the Claims Table
- Z Open the Ingredient Table
- Z View Search Forms Menu
- Z Print Product Records
- Z View Database Objects

This section describes the layout of the database and how to use the database.

To install the DSPD-A, copy the file to your hard drive or server. The Access file on the CD is saved as read-only. To disable the read-only feature, right click on the file name and click Properties. A pop-up box will appear; click on the check mark in the "Read Only" box at the bottom (this will disable the read-only feature); then click the OK button. Data entry is "turned off" so you cannot add product records using the Product Form; however, any changes that you make to the database tables will be saved.

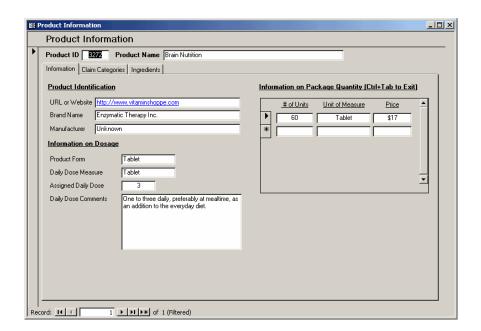
#### 5.1 VIEWING THE PRODUCT FORM

The Product Form is similar to the form that was used for data entry. From the Product Form, the user can view information about an individual product by using the tabs across the top of the form. Use the arrows at the bottom left of the screen to move from product-to-product.

#### 5.1.1 Information Tab

The Information Tab (see Figure 5-1) provides information on product form, dosage, and quantity. This part of the form displays the following information: product ID, product name, URL, brand name, manufacturer, product form, daily dose measure, assigned daily dose, daily dose comments, number of units, unit of measure (for quantity), and price. If you click on the URL, the user is automatically linked to the web site. Table 4-1 provides a description of each variable.

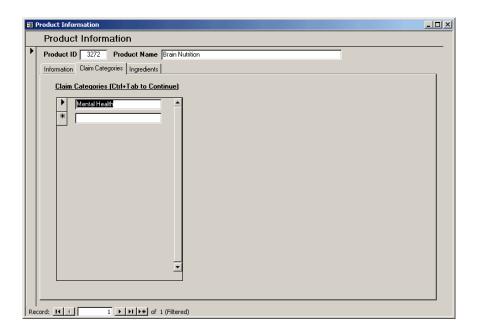
Figure 5-1. Example Information Tab in the Product Form



#### 5.1.2 Claim Categories Tab

The Claim Categories Tab (see Figure 5-2) provides information on claims made regarding the product. This part of the form displays the following information: product ID, product name, and claim categories. Table 4-3 provides the list of claims used in the database and a brief description of each claim. If no claims were made about the product on the web site, the Claim Categories box is blank.

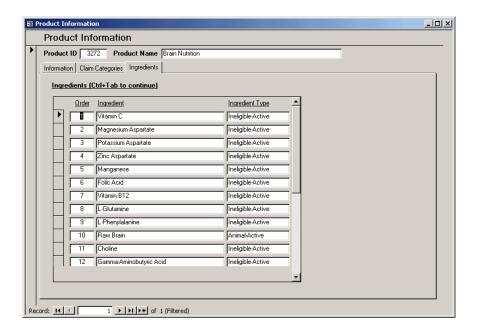
Figure 5-2. Example Claim Categories Tab in the Product Form



#### 5.1.3 Ingredients Tab

The Ingredients Tab (see Figure 5-3) provides information on the product ingredients and specific information on each eligible animal ingredient if available. This part of the form displays the following information: product ID, product name, order (numeric order of the ingredient in the list of ingredients), ingredient, and type of ingredient (animal-active, ineligible-active, or inactive).

Figure 5-3. Example Ingredients Tab in the Product Form



To view additional information on an animal-active ingredient, click on the box to the left of the numeric order of the ingredient and click the View button at the bottom of the screen. A pop-up box will appear with specific information on the animal ingredient (see Figure 5-4). From here, the user can view the following information if available: product serving size, ingredient amount per serving, ingredient form (raw or processed), animal (e.g., bovine or cervine), animal category (e.g., mammal or fish), and country of origin. If no information is available on ingredient amount, animal, and country, the "No Ingredient Information" box is checked.

Figure 5-4. Example Pop-Up Box for Animal Ingredient Information

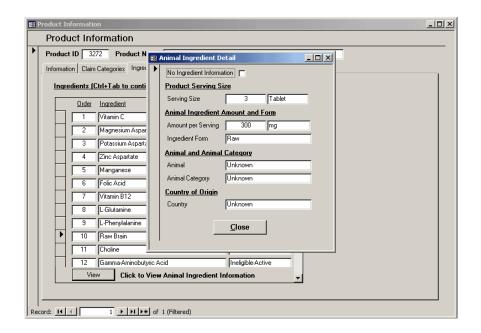


Table 4-1 provides a description of each variable included in the Ingredients Tab.

#### 5.2 VIEWING TABLES

Product information may be viewed in tabular format. This format provides selected information for each product that may be sorted and filtered to fit the user's needs. To quickly filter information in the database tables, highlight the desired field and right click on the mouse; filter options will appear. Using the keyboard Tab key will quickly move the user from field to field throughout the database.

Table 4-1 provides a description of each variable included in the Product, Claims, and Ingredient Tables.

### 5.2.1 Product Table

From the Product Table, the user can view information about all products in the database in a tabular format. The Product Table includes the following information (variable name in parentheses when clarification is needed): product ID, notebook number, date entered, brand name, manufacturer, product name, URL (RetailerID) product form (DosageFormID), assigned daily dose (AvgDailyDose), daily dose measure (AvgDailyDoseMeasure), and daily dose comments (DoseComments).

### 5.2.2 Claims Table

From the Claims Table, the user can view information about each product's claims in a tabular format. The Claims Table includes the following information: product ID and claim type.

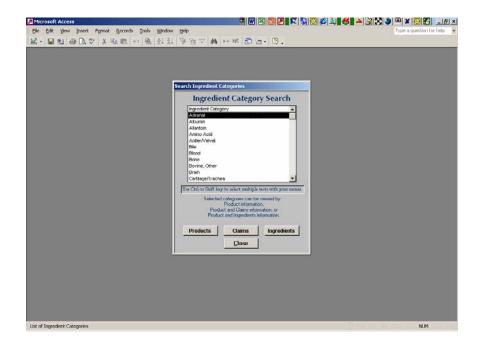
### 5.2.3 Ingredient Table

From the Ingredient Table, the user can view information about each product's ingredients in a tabular format. The Ingredients Table includes the following information (variable name in parentheses when clarification is needed): product name, ingredient, ingredient category, ingredient order, and ingredient type.

### 5.3 SEARCHING BY INGREDIENT CATEGORY

Users can search by animal ingredient category and view product, claim, and/or ingredient information in a tabular format for products containing the specified ingredient(s). This feature allows the user to quickly search for products with specific animal ingredients. To search by ingredient category, select View Search Forms Menu from the Main Menu, then select the Search by Ingredient Category option. Select the ingredient(s) of interest, then click the Products button to view product information, the Claims button to view claims information, or the Ingredients button to view ingredient information (see Figure 5-5).

Figure 5-5. Ingredient Category Search Screen



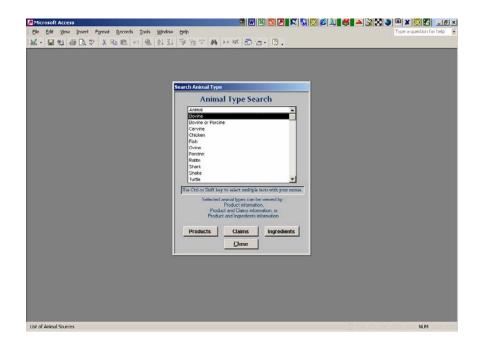
If users click "Products" the following information is provided (variable name in parentheses when clarification is needed): ingredient category, brand name, product name, product ID, product form (DosageForm), assigned daily dose (AvgDailyDose), and daily dose measure (UnitofMeasure). If users click "Claims" the following information is provided: ingredient category, product ID, product name, and claim type. If users click "Ingredients" the following information is provided: ingredient category, product name, product ID, ingredient, serving size (UnitofDose), daily dose measure (AvgDailyDoseMeasure), ingredient amount per serving (IngredientAmount), unit of measure for ingredient amount (UnitMeasureAnimalAbbrev), ingredient form, animal, animal category, and country of origin. Table 4-1 provides a description of each variable.

### 5.4 SEARCHING BY ANIMAL TYPE

Users can search by animal type (e.g., bovine or porcine) and view product, claim, and/or ingredient information in a tabular format for products containing ingredient(s) derived from the specified animal. This feature allows the user to quickly search for products with animal ingredients derived from specific animals. To search by animal type, select View Search Forms Menu from

the Main Menu, then select the Search by Animal Type option. Select the animal(s) of interest, then click the Products button to view product information, the Claims button to view claims information, or the Ingredients button to view ingredient information (see Figure 5-6). The query results provide the same information as described for the ingredient category search.

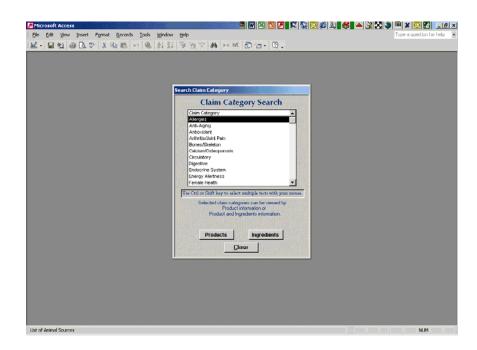
Figure 5-6. Animal Type Search Screen



### 5.5 SEARCHING BY CLAIM CATEGORY

Users can search by claim category and view product, claim, and/or ingredient information in a tabular format for products with the specified claim(s). This feature allows the user to quickly search for products with specific claims. To search by claim category, select View Search Forms Menu from the Main Menu, then select the Search by Claim Category option. Select the claim category(s) of interest, then click the Products button to view product information or the Ingredients button to view ingredient information (see Figure 5-7). The query results provide the same information as described for the ingredient category search.

Figure 5-7. Claim Category Search Screen



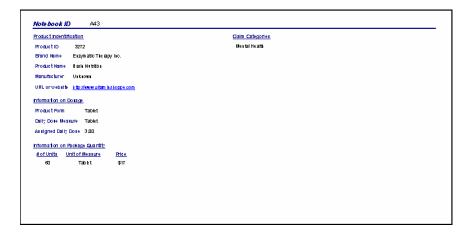
### 5.6 PRINTING PRODUCT RECORDS

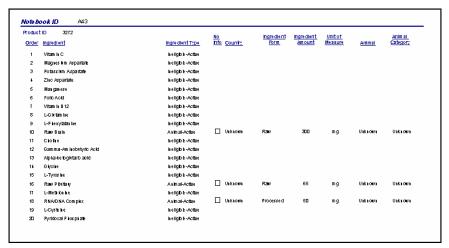
Users can print a 2-page printout that summarizes the product information contained in the database. To print, select the Print Product Records option from the Main Menu. Then, enter the product ID for the product record to be printed. To print multiple records, enter separate product IDs with a comma (e.g., 8, 10, 1230). Figure 5-8 provides an example of the product printout.

### 5.7 VIEWING DATABASE OBJECTS

From the Main Menu, select the View Database Objects option to go to the Microsoft Access menu screen. From here users can access the tables, queries, forms, and reports features of Access. Experienced users can create queries and reports and customize other aspects of the database from this menu.

Figure 5-8. Example Product Printout





### 6 Data Summary

The DSPD-A contains 3,767 records of dietary supplement products sold on the Internet that contain animal ingredients. In this section, we provide summary information on the animal ingredients contained in the products, sources of animal-derived ingredients, and claims made about products.

### 6.1 ANIMAL INGREDIENTS IN THE DSPD-A

The DSPD-A includes 6,374 animal ingredient records (some products contain more than one eligible animal ingredient). Some of the desired information on animal ingredients is not available for all products. Table 6-1 provides frequencies of animal ingredient information relative to the number of animal ingredient records. Of the DSPD-A's animal ingredient records, about 61 percent of the animal ingredients have information on ingredient amount. About 23 percent of the animal ingredients have information on animal source, and about 2 percent of the animal ingredients have information on country of origin. About 28 percent of the animal ingredients have no information on the ingredient (amount, animal, and country).

As described in Section 4, we classified each animal ingredient into one of 51 animal ingredient categories (e.g., enzyme, liver, fatty acid). Table 6-2 shows the frequency of animal ingredient categories in the DSPD-A. Because products may include multiple animal ingredients, multiple ingredient categories may be indicated for a single product. The most common animal ingredient categories are chondroitin found in 14 percent of products, followed by enzymes (12 percent), hormones (12 percent), and creatine (11 percent).

Table 6-1. Animal Ingredient Information in the DSPD-A

Animal Ingredient Information	Number of Ingredients	Percent
Ingredient Amount	3,871	61%
Animal (e.g., bovine or porcine)	1,475	23%
Animal Category (e.g., mammal or fish)	1,497	24%
Country of Origin	148	2%
Records with no animal ingredient information	1,796	28%
Total animal ingredient records	6,374	

Table 6-2. Animal Ingredient Categories by Product in the DSPD-A

Animal Ingredient Category	Number of Products	Percent
Adrenal	240	6%
Albumin	13	<1%
Allantoin	10	<1%
Amino Acid	102	3%
Antler/Velvet	66	2%
Bile	110	3%
Blood	18	<1%
Bone	149	4%
Bovine, Other	31	1%
Brain	59	2%
Cartilage/Trachea	189	5%
Cervine, Other	4	<1%
Chondroitin	540	14%
Collagen	111	3%
Creatine	428	11%
DNA/RNA	57	2%
Duodenum	53	1%
Embryo	4	<1%
Enzyme	455	12%
Eye	4	<1%
Fatty Acid	333	9%
Fish, Other	20	1%

(continued)

Table 6-2. Animal Ingredient Categories by Product in the DSPD-A (continued)

<b>Animal Ingredient Category</b>	<b>Number of Products</b>	Percent
Gelatin	215	6%
Gland, Other	29	1%
Glycerin	138	4%
Heart	63	2%
Hormone	434	12%
Kidney	82	2%
Liver	221	6%
Lung	28	1%
Lymph	38	1%
Mammary	13	<1%
Muscle/Tissue, Other	21	1%
Myelin/Central Nervous System	5	<1%
Orchic/Testicular	84	2%
Other	28	1%
Ovary	46	1%
Pancreas	325	9%
Parotid	12	<1%
Pineal	8	<1%
Pituitary	167	4%
Placenta	8	<1%
Porcine, Other	1	<1%
Prostate	62	2%
Protein	26	1%
Spleen	128	3%
Stomach	43	1%
Thalamus	29	1%
Thymus	182	5%
Thyroid	60	2%
Uterus	13	<1%
Total products	3,767	

Note: Percentages sum to more than 100 percent because a product can have more than one animal ingredient category.

### 6.2 ANIMAL SOURCES FOR PRODUCTS IN THE DSPD-A

Table 6-3 shows the frequency of animal sources (e.g., bovine or porcine) in the DSPD-A. Because products may include multiple animal ingredients from different sources, multiple animal sources may be indicated for a single product. Animal source was not available for 74 percent of the products. Percentages for each animal source are calculated relative to the number of products with animal source available. The most common animal source is bovine found in 63 percent of products, followed by shark at 17 percent.

Table 6-3. Animal Sources by Product in the DSPD-A

Animal Source	Number of Products	Percent
Bovine	607	63%
Bovine or Porcine	2	<1%
Cervine	77	8%
Chicken	17	2%
Fish	16	2%
Ovine	61	6%
Porcine	78	8%
Ratite	11	1%
Shark	164	17%
Snake	1	<1%
Turtle	1	<1%
Products with animal source	963	26%
Products with no animal source	2,804	74%
Total products	3,767	

Note: Percentages for animal source are calculated relative to the number of products with animal source available. Percentages sum to more than 100 percent because a product can have more than one animal source. For products with no animal source, the percentage is calculated relative to the total number of products.

### 6.3 PRODUCT CLAIMS IN THE DSPD-A

As described in Section 4, the claims made on products were categorized into 25 categories (e.g., antioxidant or digestive), including three FDA-allowable claims. Table 6-4 shows the frequency of claims in the DSPD-A. Products may have multiple claims; thus, multiple claim categories may be indicated for a single product. Percentages for each claim category are calculated relative to the number of products with claims. About 74 percent of products include at least one claim. Overall, the top claim categories are arthritis/joint pain (21 percent) and fitness/body building (17 percent). Less than 2 percent of products had FDA-allowable claims.

Table 6-4. Claim Categories by Product in the DSPD-A

Claim Category	Number of Products	Percent
Allergies	35	1%
Anti-Aging	123	4%
Antioxidant	189	7%
Arthritis/Joint Pain	575	21%
Bones/Skeleton	224	8%
Circulatory	325	12%
Digestive	311	11%
Endocrine System	212	8%
Energy Alertness	317	11%
Female Health	90	3%
Fitness/Bodybuilding	483	17%
Immune System	309	11%
Mental Health	333	12%
Other	359	13%
Other Organs	116	4%
Pain Relief	40	1%
Respiratory	33	1%
Sexual Function	141	5%
Skin, Hair, Nails, Teeth	152	5%
Supplementation	268	10%
Urinary Tract	57	2%
Weight Loss	255	9%
FDA-Allowable Claims		
Calcium/Osteoporosis	32	1%
Fiber/Heart Disease	3	<1%
Folic Acid/Birth Defects	2	<1%
Products with claims	2,801	74%
Products with no claims	966	26%
Total products	3,767	

Note: Percentages are calculated relative to the number of products with claims listed. Percentages sum to more than 100 percent because a product can have more than one claim. For products with no claims, the percentages are calculated relative to the total number of products.

### References

- National Nutritional Food Association's (NNFA) Committee for Product and Label Integrity. March 2001. "NNFA BSE Guidance Manual." <a href="http://www.nnfa.org/quality/BSEGuidance.pdf">http://www.nnfa.org/quality/BSEGuidance.pdf</a>>. As accessed on April 13, 2001.
- U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition (FDA, CFSAN). November 14, 2000. "Letter to Reiterate Certain Public Health and Safety Concerns to Firms Manufacturing or Importing Dietary Supplements that Contain Specific Bovine Tissues." <a href="http://www.cfsan.FDA.gov/~dms/dspltr05.html">http://www.cfsan.FDA.gov/~dms/dspltr05.html</a>>. As accessed on April 12, 2001.

## Appendix A: Web Site Worksheet

Name:	Date:
Web site:	
ID No.:	
Retailer:phone)	(print out home page with address,
Number of dietary supplements with anim	al ingredients:
Brand Name/Product Name (print out pag	es for each product)
	·
	·

# Appendix B: Product Coding Form

Notebook					
Brand Name:					
Product Name:					
Manufacturer:					
URL: www.				_	
Dosage Information:		Г			
Product Form					
Daily Dose Measure					
Unit for Ingredient Amou	unt				
Assigned Daily Dose					
Daily Dose Comments					
Information on Packaç	je Qı	uantity:			
# of Units	l	Unit of Measure	Price (rou	nded)	
Claims Categories:					
Allergies		Energy Alertnes	SS	Pain R	elief
Anti-Aging		Female Health		Respira	atory
Antioxidant		Fiber/Heart Dis	ease	Sexual	Function
Arthritis/Joint Pain		Fitness/Bodybu	ilding	Skin, H	air, Nails, Teeth
Bones/Skeleton	Bones/Skeleton		Defects	Supple	mentation
Calcium/Osteoporosis		Immune System	n	Urinary	Tract
Circulatory		Mental Health		Weight	Loss
Digestive		Other		None	
Endocrine Health		Other Organs			

Product Name:	
Animal Ingredients	Information:
Animal Ingredient	
Ingredient Amount	
Ingredient Form	Processed Raw
Animal	Unknown Bovine Caprine Cervine Fish Ovine Ratite Porcine Rodent Shark
Animal Category	Unknown Amphibian Bird Fish Mammal Reptile Other
Country of Origin	Unknown
Animal Ingredient	
Ingredient Amount	
Ingredient Form	Processed Raw
Animal	Unknown Bovine Caprine Cervine Fish Ovine Ratite Porcine Rodent Shark
Animal Category	Unknown Amphibian Bird Fish Mammal Reptile Other
Country of Origin	Unknown
Animal Ingredient	
Ingredient Amount	
Ingredient Form	Processed Raw
Animal	Unknown Bovine Caprine Cervine Fish Ovine Ratite Porcine Rodent Shark
Animal Category	Unknown Amphibian Bird Fish Mammal Reptile Other
Country of Origin	Unknown
Animal Ingredient	
Ingredient Amount	
Ingredient Form	Processed Raw
Animal	Unknown Bovine Caprine Cervine Fish Ovine Ratite Porcine Rodent Shark
Animal Category	Unknown Amphibian Bird Fish Mammal Reptile Other
Country of Origin	Unknown