

FDAMA STAKEHOLDER MEETING SUMMARY
ATLANTA, GEORGIA SITE
April 28, 1999

0000

1. FDA information packets and press kits were developed and distributed.
2. In order to facilitate a lively interactive group, a description of the program format was provided and participants were divided into 5 small workgroups where they had an opportunity to share their concerns and ask questions.
3. Each group was assigned one of the five questions provided from headquarters. and was asked to write two or three suggestions that would answer the particular question. Suggested topics were also given (e.g., partnership with other groups, ways to communicate with the public, resource allocation, priorities, and women's health and dietary supplements) to help generate comments or questions.
4. Questions and comments were immediately faxed to the live teleconference. After the teleconference, FDA expert panel responded to several questions and comments that were not addressed during the teleconference.

OUTCOME:

Total Attendees: 28

Audience Type: Participants represented industry, academia, association, health care organizations, and federal and local government.

This vigorous interactive group submitted 17 questions (via fax) during the teleconference. Attendees were pleased to hear the Commissioner respond to 5 of 17 questions submitted from the Atlanta site.

Everyone at the Atlanta location expressed appreciation for having the opportunity to watch the downlink and participate in an interactive session with other stakeholders.

The format provided all attendees the opportunity to be directly involved.

Special accommodation was provided for a "chemically sensitive" person. This person left a note of appreciation on how well she was treated by the FDA staff to her special needs.

Health Industry Manufacturers Association (HIMA) sent a complimentary letter expressing how pleased they were with the format presented at the Atlanta site. They stated that this was a worthwhile event where all participants believed that they had the opportunity to pose their questions to FDA officials.

99N-0386

sum2

STAKEHOLDERS MEETING - ATLANTA - APRIL 28, 1999

Field	Last Name	First Name	M.I.	Title	Organization Name	Address	City	State	Zip Code	Phone Number	Fax Number	Email Address
RA	Bachmon, RPH	George		Assistant Director	Grady Health Sys/Dept Pharmacy & Drug Info	80 Butler Street, SE	Atlanta	GA	30335-3801	(404) 616-5835	(404) 616-3846	
WI	Bargainier	Doris		Managed Care Specialist	DHHS/HCF	61 Forsyth Street, SW	Atlanta	GA	30303-8909	(404) 562-7377		DBARGAINIER@HCFA.GOV
RNS	Bisnot	Angeline	A.	Exec Asst	Senior Citizens Services	1705 Commerce Drive, NW	Atlanta	GA	30318-	(404) 351-3889	(404) 352-0595	BISNOTT@AOL.COM
RA	Boyd	Linda		Program Coordinator	NBLIC	720 Westview Drive	Atlanta	GA	30310-	(404) 756-5789	(404) 756-5298	BOYDL@msm.edu
RNS	Bruce	Charlene		Director, Food Protection Branch	MS State Department of Health	P. O. Box 1700	Jackson	MS	39215-1700		(601) 576-7632	cbruce@msdh.state.ms.us
RA	Cambla	Cathryn		Director, RA/QA	Biomedical Disposal, Inc.	3690 Holcomb Bridge Road	Norcross	GA	30092-	(770) 300-9595	(770) 300-9306	ccambra@bioltdsposal.com
RNS	Campos	Warley		Veterinarian		Av Contagem 1840 Balro Santa In, s	Belo Horizonte	Minas Gerais/Brazil	31080-000	(005) 531-4851		jefem@rural.com.br
RA	Carey	Michelle		Staff Assistant	Congresswoman Cynthia McKenny's Office	246 Sycamore Street, Suite 110	Decatur	GA		(404) 377-6900	(404) 377-6909	michelle.carey@mail.house.gov
RNS	Carmack	Shirley Dr.	Bradley	Founder	GNLD Wellness Center	2760 Pleasant Wood Drive	Decatur	GA	30034-	(404) 284-6272	(404) 284-0646	
RA	Carson	Cathleen	(Cathy)	Regulatory Manager	Domier Medical Systems Inc.	1155 Roberts Blvd.	Kennesaw	GA	30144-	(770) 514-6122	(770) 514-6288	ccarson@domier.com
RNS	Casarett	David		Fellow, Palliative Medicine	University of Pennsylvania	3641 Locust Walk	Philadelphia	PA	19104-	(215) 898-2583		casarett@mail.med.upenn.edu
RNS	Courtney	Suzanne		Regulatory Specialist	Domier Medical Systems Inc.	1555 Roberts Blvd.	Kennesaw	GA	30144-	(770) 514-6122	(770) 514-6288	scourtney@domier.com
RA	Davis	Peggy				1055 Gilbert Street, SE	Atlanta	GA	30316-	(404) 881-4466	(404) 881-7777	PDAVIS@ALSTON.COM
RNS	Dodemaide	W.	Robert	Manager, QA/RA	Hoechst Roussel Vet	30 Independence Blvd.	Providence	NJ	07059-	(908) 231-2997	(908) 231-4462	rdodemaide@hrvet.com
RA	Dunn	Charles		Opr Analyst/Cons Protec Div	GA Department of Agriculture	19 MLKing Jr. Drive	Atlanta	GA	30334-	(404) 656-3627	(404) 463-6428	cdunn@agri.state.ga.us
RNS	Dwyer	Kevin		VP, Regulatory Affairs	Pacific BioDevelopment	533 Airport Blvd., Suite 400	Burlington	CA	94001-	(650) 401-2234	(650) 401-2235	kdwyer@pacbiodev.com
RNS	Eaves	Martha			Georgia Council on Aging	2 Peachtree St., NW, Suite 35-457	Atlanta	GA	30303-3142	(404) 657-5343	(404) 657-1722	
RA	Ford-Roegner	Pat		Regional Director	US DHHS	61 Forsyth Street, SW, Suite 5B95	Atlanta	GA	30303-8909	(404) 562-7888	(404) 562-7899	pfordroegner@
RA	Garrettson, MD FAAP	Lorne	K.	Assoc. Professor/Dept. of Pediatrics	Emory University School of Medicine	68 Butler Street, SE	Atlanta	GA	30303-	(404) 616-4403	(404) 616-6657	
RA	Gayle	Leigh Anne		Regulatory Affairs Manager	Elekta	3155 Northwoods Pkwy., NW	Norcross	GA	30071-	(770) 300-9725	(770) 252-8424	leighann@elekta.com
RA	Gudith	Michelle		Assistant RA Manager	Innogenetics Inc.	5335 Triangle Pkwy., Suite 300	Norcross	GA	30092-	(678) 393-1672	(678) 393-1673	michelle.gudith@innogenetics.com
WI	Harris	Sharon		Manager, Regulatory Affairs	American Red Cross	1925 Monroe Drive	Atlanta	GA		(404) 253-5258	(404) 253-5369	HARRISS@ARCATL.ORG
RNS	Harris	Van		Agriculture Mgr	GA Dept Agriculture	19 MLKing Jr Dr., Room 306	Atlanta	GA	30334-	(404) 656-3632	(404) 463-6428	vharris@agr.state.ga.us
RA	Hubbard	Sharon	D.	Science Teacher	G. W. Carver High School	1275 Capitol Avenue, SW	Atlanta	GA	30315-	(404) 330-4108	(404) 330-4154	
RA	Johnson, PharmD	Steven	T.	Clinical Pharmacist Specialist	Grady Health Systems, Drug Info & Utilization	80 Butler Street, SE	Atlanta	GA	30335-3801	(404) 616-7729	(404) 616-2228	stevenjohnson@hotmail.com
RNS	Kotula	Carolann		VP, Regulatory Affairs/Quality Assur.	mdl Consultants Inc	4374 Bending River Trail	Lilburn	GA	30047-	(770) 985-8203	(770) 736-8219	ckotula@bellsouth.net
RA	Lilly	Sydney		Quality Assurance/Reg. Affairs Mgr.	Coloplast Corporation	1955 West Oak Circle	Marletta	GA	30062-	(770) 281-8400	(770) 281-8501	
RA	Mullis, Jr.	David	W.	VP, Global Clinical Affairs	London International Group Inc.	3585 Engineering Drive	Norcross	GA	30092-	(770) 448-4455	(770) 582-2233	David.Mullis@LIGPLC.com
WI	Page	Cheryl	N.	Breastect Coordinator	Fulton County Department of Health/Wellness	186 Sunset Avenue	Atlanta	GA		(404) 730-4764		
RA	Pang, PharmD	Mamie	W.	Pharmacy Practice Resident	Grady Health Sys/Dept Pharmacy & Drug Info	80 Butler St neet, SE	Atlanta	GA	30335-3801	(404) 616-3806	(404) 616-2228	
WI	Polasko	Paul		QA Officer	American Red Cross	1925 Monroe Drive	Atlanta	GA		(404) 253-5248	(404) 253-3663	POLASKOP@ARCATL.ORG
RA	Santalucia	Michael		VP, Vision Care Regulatory Affairs	Bausch & Lomb Inc.	1400 N Goodman Street	Rochester	NY	14609-	(716) 338-8731	(716) 338-0702	Michael A Santalucia@bausch.com
RA	Shafer	Mark			Domier Medical Systems, Inc./Publications	1155 Roberts Blvd.	Kennesaw	GA	30144-	(770) 514-6122	(770) 514-6288	cwernecke@domier.com
RA	Singer	Nancy		Special Counsel	Health Industry Manufacturers Association	1200 G Street NW, Suite 400	Washington	DC	20005-3814	(202) 434-7222	(202) 783-8750	nsinger@himanet.com
RNS	Smith	Gayla		Chair, Health & PE	G. W. Carver High School	1275 Capitol Avenue, SW	Atlanta	GA	30315-	(404) 330-4108	(404) 330-4154	
RNS	Smock	Cameron		Assistant Commissioner	GA Dept Agriculture	19 MLKing Jr Drive, Room 306	Atlanta	GA	30334-	(404) 656-3627	(404) 656-6428	csmock@agr.state.ga.us
WI	Smokler	Jeanne			Rehall Independent Distributor	2210 Piedmont Forest	Marletta	GA	30062-	(770) 977-9229	(000) 000-0000	
RNS	Speaks	Don		Assistant Director	Emory Healthcare	101 W Ponce de Leon, Suite 300	Decatur	GA	30030-	(404) 778-5433	(404) 778-2241	
RA	Strander	John	O.		World-Wide Clinical Trials	500 Chastain Blvd., Suite 555	Kennesaw	GA	30144-	(770) 426-7799		
RNS	Strayer	Lydia		Bureau Dir., Gen. Environmental Serv.	MS State Department of Health	P.O.Box 1700	Jackson	MS	39215-1700	(601) 576-7690	(601) 576-7632	lstrayer@msdh.state.ms.us
RA	Tracey	Karen	L.		FDA, Office of Management Systems	5600 Fishers Lane, Rm. 16B06	Rockville	MD	20857-001	(301) 827-3431		
RA	Vierling	Carol		Manager, Regulatory Affairs	C. R. Bard	13183 Harland Drive	Covington	GA	30014-	(770) 385-2347	(770) 385-2340	carol.vierling@crbard.com
RNS	Waters III	William		Physician	Harrison & Waters PC	35 Collier Road, Suite 150	Atlanta	GA	30309-	(404) 355-1966	(404) 603-2807	drwaters@mindspring.com
RNS	Wiley, RN	Virginia	F.	Director	Institutional Review Board	CCC-3322 Medical Center North	Nashville	TN	37232-2103	(615) 343-2648		virginia.wiley@mcmail.vanderbilt.edu
RA	Woodward	Betsy		AFDO Executive Director	Association of Food/Drug Officials	1238 Sedgewick Road	Tallahassee	FL	32311-	(850) 878-7440	(850) 878-1763	SMTPE@FDAORAHQ05@Servers[chum@msn.com]
RNS	Yert	Harold		Assistant Division Director	GA Dept Agriculture	19 MLKing Jr. Drive	Atlanta	GA	30334-	(404) 656-3621	(404) 463-6428	hyert@agr.state.ga.us

RA = REGISTERED ATTENDEE

RNS = REGISTERED NO-SHOW

W/I = WALK-IN

TOTAL ATTENDEES = 28

1 From 5/17/91 [Redacted]
Date 5/17/91
Sender's Name JoAnn Pittman **Phone** (404) 253-1272
Company FOOD & DRUG ADMINISTRATION
Address 60 8TH ST NE
City ATLANTA **State** GA **ZIP** 30309

2 Your Internal Billing Reference Information

3 To
Recipient's Name Jennie Butler (HFA-305) **Phone** (301) 827-6880
Company Food and Drug Administration
Address 5600 Fishers Lane, FHSL Bldg. Room 10-61
City Rockville **State** MD **ZIP** 20857-001

For HOLD at FedEx Location check here
 Hold Weekday (Not available with FedEx First Overnight)
 Hold Saturday (Not available at all locations) (Available for FedEx Priority Overnight and FedEx 2Day only)
For WEEKEND Delivery check here
 Saturday Delivery (Available for FedEx Priority Overnight and FedEx 2Day only)
 NEW Sunday Delivery (Available for FedEx Priority Overnight only)



4a Express Package Service Packages under 150 lbs. Delivery commitment may be later in some areas.
 FedEx Priority Overnight (Next business morning)
 FedEx Standard Overnight (Next business afternoon)
 FedEx First Overnight (Earliest next business morning delivery to select locations) (Higher rates apply)
 FedEx 2Day (Second business day)
 FedEx Express Saver (Third business day)
 FedEx Enter Rate not available. Minimum charge: One pound rate.

4b Express Freight Service Packages over 150 lbs. Delivery commitment may be later in some areas.
 FedEx Overnight Freight (Next business day)
 FedEx 2Day Freight (Second business day)
 FedEx Express Saver Freight (Up to 3 business days)
 (Call for delivery schedule. See back for detailed descriptions of freight services.)

5 Packaging
 FedEx Letter
 FedEx Pak
 FedEx Box
 FedEx Tube
 Other Pkg.
 Declared value limit \$500

6 Special Handling (One box must be checked)
 Does this shipment contain dangerous goods? No Yes (As per attached Shipper's Declaration) Yes (Shipper's Declaration not required)
 Dry Ice (Dry Ice, 9, UN 1845) x kg. Cargo Aircraft Only
 *Dangerous Goods cannot be shipped in FedEx packaging.

7 Payment
Bill to: Sender (Account No. in Section 1 will be billed) Recipient (Enter FedEx Account No. or Credit Card No. below) Third Party Credit Card Cash/Check
 Obtain Recipient FedEx Account No.



Total Packages **Total Weight** **Total Declared Value** **Total Charges**
 \$.00 \$
 When declaring a value higher than \$100 per shipment, you pay an additional charge. See SERVICE CONDITIONS, DECLARED VALUE, AND LIMIT OF LIABILITY section for further information.
 Credit Card Auth.

8 Release Signature

Your signature authorizes Federal Express to deliver this shipment without obtaining a signature and agrees to indemnify and hold harmless Federal Express from any resulting claims.
Questions?
 Call 1-800-Go-FedEx® (800)463-3339
 0079815974

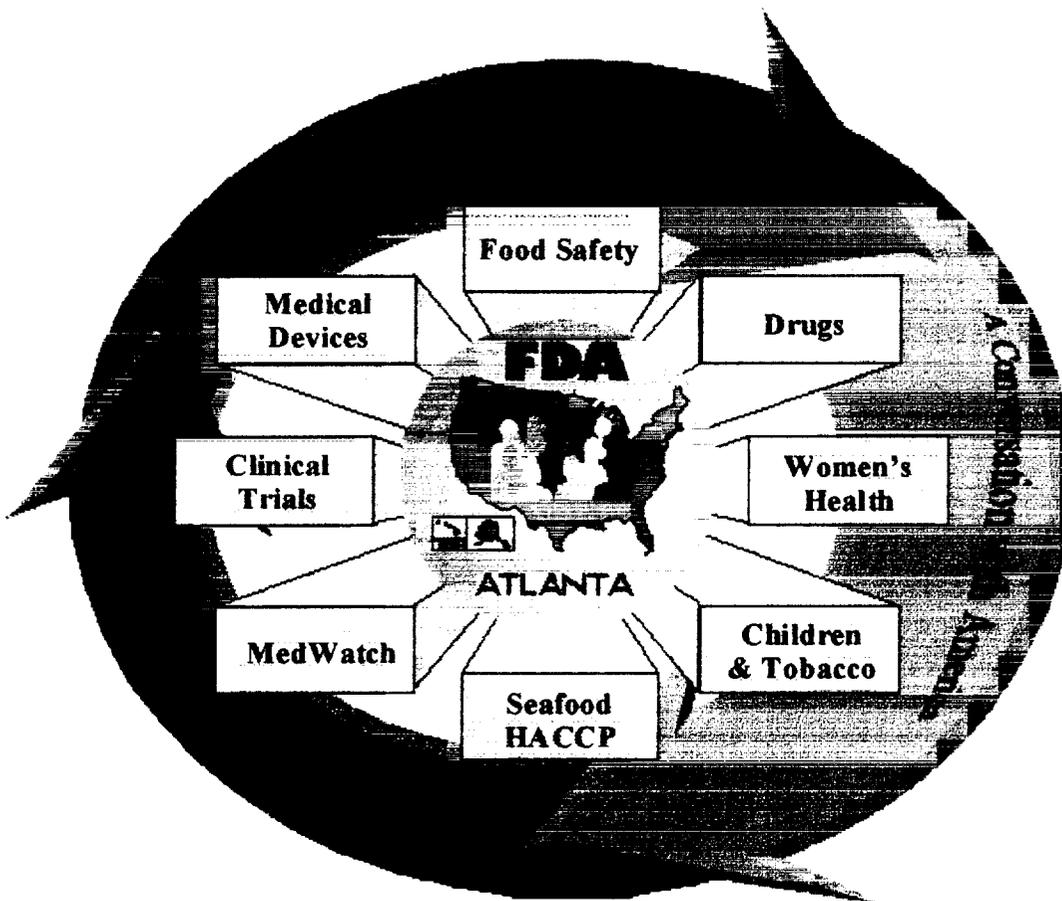
321

fdama

U.S. Food and Drug Administration

Southeast Regional Stakeholders Meeting

Talking with Stakeholders about FDA Modernization



April 28, 1999
FDA Atlanta Field Office
Atlanta, Georgia

sponsored by

Office of the Commissioner
Office of Regulatory Affairs
Atlanta Field Office

speakers from

Association of Food & Drug Officials
Health Industry Manufacturers Association

TAS

U.S. Food and Drug Administration

fdama Southeast Regional Stakeholders Meeting Agenda

The Food and Drug Administration Modernization Act of 1997

Talking with Stakeholders about FDA Modernization

Atlanta Field Office

Wednesday, April 28, 1999

12:00 noon to 5:30 p.m.

Live Satellite Teleconference with FDA Commissioner Jane E. Henney, M.D.

1:00 p.m. to 3:00 p.m. EST

REGISTRATION

PLENARY SESSION I

FDA's Opening Remarks

Ballard Graham, Acting Regional Food and Drug Director, Southeast Region

Gary Dykstra, Deputy Associate Commissioner for Regulatory Affairs

Joseph Baca, Director, Dallas District (Field Food Committee)

JoAnn Pittman, Public Affairs Specialist, Atlanta District

Interactive Satellite Teleconference

BREAK *Light refreshments served*

PLENARY SESSION II*

Panel: "Continuing the Dialogue"

Presentation: State Affiliation

Betsy Woodward, Executive Director

Association of Food & Drug Officials (AFDO)

Presentation: Trade Association

Nancy Singer, Special Counsel

Health Industry Manufactures Association (HIMA)

Working Session: Public Feedback**

Open Forum

CLOSING REMARKS

* Official Recording for Docket No. 99N-0386, Donovan Reporting, 237 Roswell Street, Marietta, GA 30060

** Stakeholder questions (Reference: March 22, 1999, Federal Register notice)



Atlanta District Office
60 Eighth Street, NE
Atlanta, GA 30309

March 31, 1999

Dear FDA Partner:

This is to invite you to participate in a live satellite teleconference sponsored by the Food and Drug Administration on April 28, 1999, from 1-3 p.m. Eastern Time, at the FDA Atlanta District Office. See directions enclosed. Registration will be held from 12:00 noon to 12:30 p.m. An overview of the program outline will begin at 12:30 p.m. and the open forum will continue after the teleconference through 5:00 p.m. Refreshments will be served.

FDA Commissioner Jane E. Henney, M.D., and Associate Commissioner for Strategic Management Linda A. Suydam, D.P.A., will host the interactive teleconference. Dr. Henney will discuss her priorities, opportunities and challenges to FDA as it enters the new century.

This is part of an ongoing discussion begun last summer with FDA stakeholders, including representatives of consumer groups, the regulated industry, health professionals, state and local government and academia, about FDA's modernization efforts. The teleconference will be broadcast simultaneously in all time zones. A flyer on the teleconference is enclosed and provides further information.

In conjunction with the national videoconference, Directors of FDA's Centers will meet with stakeholders at eight local meetings across the country on the same day as the broadcast. These local meetings will link to the interactive teleconference and provide an opportunity for discussion between stakeholders and senior FDA leaders via telephone and fax. Information on the stakeholder meetings, locations and times of these meetings and guidance on participation is also enclosed. Please complete the enclosed registration form and return to JoAnn Pittman via fax at (404) 253-1202 or via e-mail: jpittman@ora.fda.gov on or before April 23, 1999.

The purpose of these local meetings is to report to stakeholders on FDA's progress in implementing FDAMA and the Agency's strategic direction in the future, and to seek stakeholder input on two key themes: strengthening the science and analytical base of FDA and improving processes for communicating with the public. The following questions will serve as the focus of discussion at these meetings:

- 1) **What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decision-making?**

FDA Stakeholder Letter

March 31, 1999

Page 2

- 2) **What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's life cycle?**
- 3) **What actions do you propose for educating the public about the concept of balancing risks against benefits in public health decision-making?**
- 4) **What actions do you propose to enable FDA and its product Centers to focus resources on areas of greatest risk to the public health?**
- 5) **What additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?**

Please consult FDA's web page <http://www.fda.gov>: *FDAMA* for more updated information about the meetings. We look forward to meeting with you and hearing your ideas and suggestions on how FDA can better protect the public health.

Sincerely yours,



Ballard H. Graham
Acting Regional Food and Drug Director
Southeast Region

Enclosures



The FDA Modernization Act of 1997

November 21, 1997

The FDA Modernization Act of 1997 is a major legislation focused on reforming the regulation of food, medical products, and cosmetics. The following are the most important provisions of the act:

Prescription Drug User Fees

The act reauthorizes, for five more years, the Prescription Drug User Fee Act of 1992 (PDUFA). In the past five years, the program has enabled the agency to reduce to 15 months the 30-month average time that used to be required for a drug review before PDUFA. This accomplishment was made possible by FDA managerial reforms and the addition of 696 employees to the agency's drugs and biologics program, which was financed by \$329 million in user fees from the pharmaceutical industry.

FDA Initiatives and Programs

The law enacts many FDA initiatives undertaken in recent years under Vice President Al Gore's Reinventing Government program. The codified initiatives include measures to modernize the regulation of biological products by bringing them in harmony with the regulations for drugs and eliminating the need for establishment license application; eliminate the batch certification and monograph requirements for insulin and antibiotics; streamline the approval processes for drug and biological manufacturing changes; and reduce the need for environmental assessment as part of a product application.

The act also codifies FDA's regulations and practice to increase patient access to experimental drugs and medical devices and to accelerate review of important new medications. In addition, the law provides for an expanded database on clinical trials, which will be accessible by patients. With the sponsor's consent, the results of such clinical trials will be included in the database. Under a separate provision, patients will receive advance notice when a manufacturer plans to discontinue a drug on which they depend for life support or sustenance, or for a treatment of a serious or debilitating disease or condition.

Information on Off-label Use and Drug Economics

The law abolishes the long-standing prohibition on dissemination by manufacturers of information about unapproved uses of drugs and medical devices. The act allows a firm to disseminate peer-reviewed journal articles about an off-label indication of its product, provided the company commits itself to file, within a specified time frame, a supplemental application based on appropriate research to establish the safety and effectiveness of the unapproved use.

The act also allows drug companies to provide economic information about their products to formulary committees, managed care organizations, and similar large-scale buyers of health-care products. The provision is intended to provide such entities with dependable facts about the economic consequences of their procurement decisions. The law, however, does not permit the dissemination of economic information that could affect prescribing choices to individual medical practitioners.

Pharmacy Compounding

The act creates a special exemption to ensure continued availability of compounded drug products prepared by pharmacists to provide patients with individualized therapies not available commercially. The law, however, seeks to prevent manufacturing under the guise of compounding by establishing parameters within which the practice is appropriate and lawful.

Risk-based Regulation of Medical Devices

The act complements and builds on FDA's recent measures to focus its resources on medical devices that present the greatest risks to patients. For example, the law exempts from premarket notification class I devices that are not intended for a use that is of substantial importance in preventing impairment of human health, or that do not present a potential unreasonable risk of illness or injury. The law also directs FDA to focus its postmarket surveillance on higher risk devices, and allows the agency to implement a reporting system that concentrates on a representative sample of user facilities—such as hospitals and nursing homes—that experience deaths and serious illnesses or injuries linked with the use of devices.

Finally, the law expands an ongoing pilot program under which FDA accredits outside—so-called "third party"—experts to conduct the initial review of all class I and low-to-intermediate risk class II devices. The act, however, specifies that an accredited person may not review devices that are permanently implantable, life-supporting, life-sustaining, or for which clinical data are required.

Food Safety and Labeling

The act eliminates the requirement of FDA's premarket approval for most packaging and other substances that come in contact with food and may migrate into it. Instead, the law establishes a process whereby the manufacturer can notify the agency about its intent to use certain food contact substances and, unless FDA objects within 120 days, may proceed with the marketing of the new product. Implementation of the notification process is contingent on additional appropriations to cover its cost to the agency. The act also expands procedures under which FDA can authorize health claims and nutrient content claims without reducing the statutory standard.

Standards for Medical Products

While the act reduces or simplifies many regulatory obligations of manufacturers, it does not lower the standards by which medical products are introduced into the market place. In the area of drugs, the law codifies the agency's current practice of allowing in certain circumstances one clinical investigation as the basis for product approval. The act, however, does preserve the presumption that, as a general rule, *two* adequate and well-controlled studies are needed to prove the product's safety and effectiveness.

In the area of medical devices, the act specifies that FDA may keep out of the market products whose manufacturing processes are so deficient that they could present a serious health hazard. The law also gives the agency authority to take appropriate action if the technology of a device suggests that it is likely to be used for a potentially harmful unlabeled use.

U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: March 3, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99-6808 Filed 3-19-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-0386]

Talking With Stakeholders About FDA Modernization; Notice of Meetings and Teleconference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings and teleconference.

SUMMARY: The Food and Drug Administration (FDA) is announcing public meetings and an interactive satellite teleconference entitled "Talking With Stakeholders About FDA Modernization." The purpose of the meeting is to discuss the agency's progress in implementing the FDA Modernization Act (FDAMA) and to seek additional input on specific FDAMA performance targets.

DATES: The meetings and teleconference will be held on April 28, 1999. The deadlines for speaker registration and attendance registration are April 9, 1999, and April 16, 1999, respectively. Stakeholders interested in being a member of the studio audience should indicate their interest by April 15, 1999. Comments may be submitted by May 14, 1999. For additional information regarding registration, the meetings, and teleconference, see Table 1 in section III of this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, e-mail "FDADockets@bangate.fda.gov", or via the FDA web site "http://www.fda.gov".

FOR FURTHER INFORMATION CONTACT: Carrie Smith Hanley, Office of External Affairs (HF-60), Food and Drug Administration, 5600 Fishers Lane,

Rockville, MD 20857, 301-827-3365, FAX: 301-594-0113, e-mail: "chanley@oc.fda.gov".

SUPPLEMENTARY INFORMATION:

I. Background

Section 406(b) of FDAMA (21 U.S.C. 393(f) and (g)) requires the agency: To consult with its external stakeholders as it moves forward to modernize the agency; to develop a plan, based on input from stakeholders, for complying with the agency's obligations under the Federal Food, Drug, and Cosmetic Act (the act); and to periodically revisit the plan in consultation with stakeholders to make appropriate adjustments. As a culmination of these requirements, FDA will issue a performance report to Congress at the end of the 1999 calendar year.

A summary of the agency's responses to each obligation follows.

A. Consult With External Stakeholders

To respond to the first requirement of section 406(b) of FDAMA, the agency held a series of well attended public meetings last summer to obtain stakeholder views on how FDA can best meet its statutory obligations. Stakeholders offered a wealth of productive suggestions, many of which reflect their desire for greater involvement in FDA's work by contributing to the agency's future strategies and for receiving clear and timely information about the agency's processes and new regulated products.

B. Develop a Plan That Reflects Stakeholders Views

FDA listened carefully to its stakeholders and used their contributions to guide the development of a plan for complying with its obligations under FDAMA, as well as responding to the public's expectations. In the Federal Register of November 24, 1998 (63 FR 65000), the agency published the "FDA Plan for Statutory Compliance" (see FDA's web site, "http://www.fda.gov/oc/fdama/fdamapln"). This plan provides a broad, agency wide strategic framework and specific performance goals for the current fiscal year (1999) that will allow FDA to act on stakeholder recommendations as well as allow the agency to meet its statutory obligations. The strategic framework outlines six broad directions: Strengthening the science base, closely collaborating with stakeholders, establishing risk-based priorities, adopting a systems approach, continuing to reengineer FDA processes, and capitalizing on information technology. The plan describes how the agency is already implementing many

strategies in new and creative ways within each of these broad directions.

C. Periodically Revisit the Plan in Consultation with Stakeholders

FDA is now preparing to revisit the 406(b) plan as part of a formal consultation with its stakeholders on April 28, 1999. The agency would like to receive input from stakeholders on the elements of the plan that have been implemented thus far and obtain additional suggestions on how the agency can continue to improve its modernization efforts. FDA specifically wants input on how to: (1) Strengthen its science base and (2) Improve its communication processes. To help focus the discussion at the April 28, 1999, meeting, FDA has designed five questions that address these two concerns. As stakeholders respond to these questions, it may be useful to review the "FDA Plan for Statutory Compliance" which outlines the agency's current and proposed activities in these two areas. FDA requests that stakeholders address the five questions below in their oral and/or written views:

1. Science based decisions are made throughout the life span of products from initial research, development and testing, through production, marketing, and consumption. These decisions require the best science to identify, evaluate, and balance product risks and benefits. It is crucial that FDA, in collaboration with product sponsors, develop a shared understanding of new science and technologies and their effect throughout a product's life span.

What actions do you propose the agency take to expand FDA's capability to incorporate state-of-the-art science into its risk-based decisionmaking?

2. As the agency attempts to meet its public health responsibilities, the speed of discovery results in an avalanche of new information from government, academic, and industry scientists.

What actions do you propose to facilitate the exchange and integration of scientific information to better enable FDA to meet its public health responsibilities throughout a product's lifecycle?

3. Most products in the American marketplace, especially medical ones, have two facets. On one side they benefit users and often improve lives. They are, however, rarely without risk, and their use can result in known and unknown side effects. Consumers must weigh benefits and risks before using these products, oftentimes with incomplete information.

What actions do you propose for educating the public about the concept

of balancing risks against benefits in public health decisionmaking?

4. The agency stated in the "FDA Plan for Statutory Compliance" that inflation has eroded real assets that can be applied to meet its public health mission while Congress has increased its responsibilities.

Because the agency must allocate its limited resources to achieve the greatest impact, what actions do you propose to enable FDA and its product centers to focus resources on areas of greatest risk to the public health?

5. FDAMA requires the agency to continue to meet with stakeholders on key issues. Meetings have ranged from explaining the positions of the agency on particular issues to working with sponsors on product applications. Historically, these interactions have benefited both stakeholders, through better knowledge of FDA, and the agency, by leading to positive changes in its operations.

Because the agency wants to assure that its stakeholders are aware of and participate in its modernization activities, what additional actions do you propose for enhancing communication processes that allow for ongoing feedback and/or evaluation of our modernization efforts?

II. Comments

Stakeholders are encouraged to submit their responses in advance of the April 28, 1999, meeting. Written comments should be identified with docket number 99N-0386 and submitted to the Dockets Management Branch (address above). In order to promote a variety of responses, stakeholders are encouraged to state a proposed action as a separate concise statement followed by a written explanation of its meaning.

III. Scheduled Meetings

Open public meetings with stakeholders will be held in several

locations throughout the country. These meetings will provide down-link interactive viewing sites for the live satellite teleconference and also provide an opportunity for formal presentations to FDA's senior managers at the local meetings. The teleconference will feature Jane E. Henney, Commissioner of Food and Drugs, and Linda A. Suydam, Associate Commissioner for Strategic Management, who will be talking with stakeholders during the live satellite teleconference. These meetings are open to all stakeholders and will be co-hosted by FDA's field offices and centers, and they will focus on the specific product center listed in the first column of Table 1 of this document. The scheduled time of meetings, as listed in Table 1 of this document, includes the time devoted to the live satellite teleconference broadcast, as well as a period of time for presentations and/or discussion of the questions listed in section I.C of this document.

TABLE 1

Center/City Registration	Location/Address	Scheduled Time Of Meeting	Speaker Registration Contact	Attendance Contact
Center for Drug Evaluation and Research, Philadelphia, PA	Temple University, Main Campus, Ritter Hall, Kiva Auditorium, 130 Cecil B. Moore Ave., Philadelphia, PA	12:30 p.m. to 6 p.m. Eastern Time	Marcia Trenter, Phone: 301-827-1492, Fax: 301-827-3056, Email: Trenterm@cder.fda.gov	Anitra Brown-Reed, Phone: 215-597-4390 ext. 4202, Fax: 215-597-4660, Email: Abrown2@ora.fda.gov
Center for Biologics Evaluation and Research, Boston, MA	Boston University, School of Medicine, 715 Albany St., Boston, MA	9:30 a.m. to 3 p.m. Eastern Time	Lorrie Harrison, Phone: 301-827-5546, Fax: 301-827-3079, Email: Harrison@cber.fda.gov	Lorrie Harrison, Phone: 301-827-5546, Fax: 301-827-3079, Email: Harrison@cber.fda.gov
Center for Biologics Evaluation and Research, San Francisco, CA	South San Francisco Conference Ctr., 255 South Airport Blvd., South San Francisco, CA	9:30 a.m. to 3 p.m. Pacific Time	Lorrie Harrison, Phone: 301-827-5546, Fax: 301-827-3079, Email: Harrison@cber.fda.gov	Lorrie Harrison, Phone: 301-827-5546, Fax: 301-827-3079, Email: Harrison@cber.fda.gov
Center for Food Safety and Applied Nutrition, Chicago, IL	Ralph Metcalfe Federal Bldg., 77 West Jackson Blvd., Morrison Conference Room, Chicago, IL	12 Noon to 4:30 p.m. Central Time	Marquita Steadman, Phone: 301-827-6735, Fax: 301-480-5730, Email: msteadman@bangate.fda.gov	Kimberly Phillips, Phone: 312-353-7126 ext. 183, Fax: 312-886-3280, Email: Kphillip@ora.fda.gov
Center for Veterinary Medicine, Overland Park, KS	Johnson County Community College, Bldg. CE, rm. 211, 12345 College Blvd., (Kansas City, KS) (111th & Quivera), Overland Park, Kansas (Kansas City, KS)	11:30 a.m. to 5 p.m. Central Time	Linda Grassie, Phone: 301-827-6513, Fax: 301-594-1831, Email: Lgrassie@bangate.fda.gov	Linda Grassie, Phone: 301-827-6513, Fax: 301-594-1831, Email: Lgrassie@bangate.fda.gov
Center for Devices and Radiological Health, San Diego, CA	Scripps Research Institute, Shepherd Great Hall, Schaetzle Education Center, Scripps Memorial Hospital, 9890 Genesee Ave., La Jolla, CA, (San Diego)	9:45 a.m. to 4 p.m. Pacific Time	Ron Jans, Phone: 301-827-0048, Fax: 301-443-8810, Email: Rsj@cdrh.fda.gov	Ron Jans, Phone: 301-827-0048, Fax: 301-443-8810, Email: Rsj@cdrh.fda.gov

TABLE 1—Continued

Center/City Registration	Location/Address	Scheduled Time Of Meeting	Speaker Registration Contact	Attendance Contact
Office of Regulatory Affairs, Atlanta, GA	Food and Drug Administration, 60 Eighth St., N.E. Atlanta, GA	12 noon to 5 p.m. Eastern Time	Joann Pittman, Phone: 404-253-1272, Fax: 404-253-1202, Email: jpittman@ora.fda.gov	Joann Pittman, Phone: 404-253-1272, Fax: 404-253-1202, Email: jpittman@ora.fda.gov
FDA General, Washington, DC	United States Department of Agriculture, Jefferson Auditorium (West Wing), 14th and Independence Ave., SW., Washington, DC	12:30 p.m. to 5:30 p.m. Eastern Time	Mary Gross, Phone: 301-827-3364, Fax: 301-594-0113, Email: mgross@oc.fda.gov	Russell Campbell, Phone: 301-827-4413, Fax: 301-443-9767, Email: rcampbe2@oc.fda.gov

A separate FDAMA section on the FDA web site will provide current information about these public meetings. It is highly recommended that individuals who wish to participate at these public meetings plan to attend the entire session. Each public meeting will include an opportunity for an open comment session where attendees can express their views.

The Interactive satellite teleconference is a C-Band broadcast with the following coordinates: satellite GE-2, 85 West, Transponder 3, frequency 3760 MHz Vertical. Test signal begins at 12 noon Eastern Time. The satellite teleconference will begin promptly at 1 p.m. Eastern Time and end no later than 3:30 p.m. Eastern Time. Limited seating will be available for a live studio audience at the broadcast studio in Gaithersburg, MD. Individuals representing broad interest groups are invited to participate in the studio audience. A balanced representation of FDA stakeholders will be selected. Stakeholders who are interested in participating in the broadcast as a member of the studio audience should indicate their interest by April 15, 1999, to Carrie Smith Hanley, Office of External Affairs at the phone, fax or e-mail address listed in the section of this document entitled "For Further Information Contact".

IV. Registration and Requests for Oral Presentations

All participants should send registration information (including name, title, firm name, address, telephone and fax number) to the appropriate "attendance registration" contact person listed in section III of this document by April 16, 1999. If you need special accommodations due to a disability, please indicate such at the time of registration.

Participants who wish to make a formal oral presentation should register with the appropriate contact for "speaker registration" identified by

meeting in section III of this document by April 9, 1999. Formal oral presentations will not be made at the studio. Stakeholders wishing to make presentations should make their wishes known to the appropriate individuals listed in section III of this document.

V. Transcripts

Transcripts of the meetings (from each site listed in section III of this document) may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page. The transcript of the meeting will be available for public examination at the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday, as well as on the FDA web site "<http://www.fda.gov>".

Dated: March 17, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99-7038 Filed 3-18-99; 11:48 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory body scheduled to meet during the month of April 1999:

Name: Council on Graduate Medical Education.

Date and Time: April 14, 1999, 8:30 a.m.—5:15 p.m. April 15, 1999, 8:30 a.m.—12 p.m.

Place: Washington Plaza, 10 Thomas Circle, N.W., Massachusetts Avenue & 14th Street, Washington, D.C.

This meeting is open to the public.

Agenda: The agenda will include:

Welcome and opening comments from the Administrator, Health Resources and Services Administration, the Associate Administrator for Health Professions and the Acting Executive Secretary of COGME; a panel on Ambulatory Settings, the Changing Environment, and Accreditation and Certification in GME; a panel on GME Physician Workforce Assessment Activities; and a panel on The Physician Public Health Workforce. The Council will hear the reports of its work groups on Ambulatory Programs and Financing, and Physician Workforce. The Council will also hear an update on Legislative Proposals and Activities. It will discuss the COGME 15th Report outline and its future direction.

Anyone requiring information regarding the subject should contact Stanford M. Bastacky, D.M.D., M.H.S.A., Executive Secretary, telephone (301) 443-6326, Council on Graduate Medical Education, Division of Medicine, Bureau of Health Professions, Room 9A-27, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

Agenda items are subject to change as priorities dictate.

Dated: March 16, 1999.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99-6809 Filed 3-19-99; 8:45 am]

BILLING CODE 4160-15-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health

JANE E. HENNEY, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
Department of Health and Human Services



Dr. Henney began her tenure as Commissioner of the Food and Drug Administration (FDA) in November of 1998. Prior to that, she served as the first Vice President of the University of New Mexico Health Sciences from 1994 to 1998. Before joining the University, Dr. Henney served as the Deputy Commissioner for Operations at FDA from 1992 to 1994. Dr. Henney's other past academic administrative positions have included Vice Chancellor for Health Programs and Policy at the University of Kansas, and Acting Director of the University of Kansas Mid America Cancer Center from 1985 to 1992. She also served as Interim Dean of the School of Medicine at the University of Kansas from 1987 to 1989. From 1976 to 1985, Dr. Henney held various positions at the National Cancer Institute (NCI) of the National Institutes of Health. From 1980-1985, Dr. Henney was Deputy Director of the NCI.

In addition to being an active member of many professional societies, Dr. Henney has been the President of the United States Pharmacopeial Convention, a member of the Advisory Committee to the Director for the National Institutes of Health, a member of the National Advisory Research Resources Council, and a member of the American Cancer Society National Board of Directors. She has served as a member of the Board of Directors of the Lovelace Respiratory Institute, the Kansas Health Foundation, and the Kansas State University Cancer Center. Dr. Henney also has served on an Advisory Committee for The Commonwealth Fund and as a consultant to the W.K. Kellogg Foundation. She currently serves as a member of the Board of Trustees at Manchester College.

Dr. Henney is a graduate of Indiana University School of Medicine and Manchester College. She completed her medical internship at St. Vincent's Hospital, and her residency at Georgia Baptist Hospital. Dr. Henney was a Fellow in Medical Oncology at M.D. Anderson Hospital and Tumor Institute, and completed graduate medical work at the Cancer Therapy Evaluation Program at NCI. She has also completed management training at the John F. Kennedy School of Government at Harvard University.

In addition to other distinguished honors, Dr. Henney was recently given an Honorary Fellowship from the American College of Healthcare Executives. She also received the Indiana University Medical School Distinguished Alumni Award in 1998, the Manchester College Alumni Award in 1996, and was a member of the Leadership New Mexico Inaugural Class in 1996-1997. She was also a member of the Charter Class for the Academic Health Centers Scholars in Academic Administration and Health Policy in 1991. Dr. Henney received the Public Health Service Commendation Medal in 1979 and 1981, and the Commissioner's Special Citation in 1994.

DR. LINDA A. SUYDAM
Associate Commissioner for Strategic Management
Food and Drug Administration
Department of Health and Human Services



As Associate Commissioner for Strategic Management, Dr. Suydam is responsible for the development and implementation of processes to execute change and develop new regulatory strategies for the Food and Drug Administration (FDA) to efficiently and effectively operate within a global economy. Dr. Suydam advises the Commissioner, Deputy Commissioner for Management and Systems and other key officials of the Agency on all matters concerning strategic management. One of her principal responsibilities is the development of the initial Agency plan required under Section 406(b) of the Food and Drug Administration Modernization Act of 1997.

Before rejoining the Agency in July 1998, Dr. Suydam was the Associate Vice President for Planning and Development of the Health Sciences Center (HSC) at the University of New Mexico in Albuquerque. The HSC is the only comprehensive patient care, education, and research health care organization in the state of New Mexico. This organization has 6,000 employees and a 500 million-dollar budget. Dr. Suydam was responsible for strategic and facilities planning, marketing, public relations, development, research coordination, the animal research facility and the HSC Library.

Dr. Suydam's career at the FDA prior to 1995 spanned 17 years of more progressive responsibility beginning in the Bureau of Medical Devices as a Program Analyst; six years as the Executive Officer for the Center for Devices and Radiological Health; two years as the Associate Commissioner for Operations in the Office of the Commissioner; and culminating as the Interim Deputy Commissioner for Operations from April 1994 until September 1995. During her FDA career Dr. Suydam received numerous awards, including the Secretary's Distinguished Service Award, the Public Health Service's Superior Service Award, two individual FDA Awards of Merit, and many group awards.

Prior to joining FDA in 1978, Dr. Suydam held progressively responsible professional positions in the private sector as a counseling administrator, social work supervisor and caseworker.

Dr. Suydam received a BA degree from Trenton State College in 1969, an MA from George Washington University in 1979, an MPA from the University of Southern California (USC) in 1983 and a DPA from USC in 1998. She is married to Dr. Gerald L. Barkdoll and resides in Rockville, Maryland.

GARY DYKSTRA
Deputy Associate Commissioner for Regulatory Affairs
Food and Drug Administration
Department of Health and Human Services

Mr. Dykstra graduated from Michigan State University with a B.S. degree in microbiology. He received his M.S. degree from Purdue University also in microbiology.

Mr. Dykstra joined Food and Drug Administration (FDA) in 1967 as a microbiologist in the Detroit District Laboratory. He moved to FDA headquarters in Rockville, Maryland in 1972. He worked in FDA's Office of Regulatory Affairs as a Special Assistant to the Associate Commissioner for Regulatory Affairs. In 1984, Mr. Dykstra joined the FDA Center for Veterinary Medicine as the Deputy Associate Director for Surveillance and Compliance. In January 1991, Mr. Dykstra became the Deputy Associate Commissioner for Regulatory Affairs.

BALLARD H. GRAHAM
Atlanta District Director
Office of Regulatory Affairs
Food and Drug Administration
Department of Health and Human Services

Ballard H. Graham is responsible, under the general guidance and direction of the Regional Food and Drug Director, for providing executive leadership and managerial direction necessary to assure the effective accomplishment of FDA's programs and enforcement activities in Georgia, North Carolina, and South Carolina. From 1966 to 1970, Mr. Graham served in the U.S. Navy as a Medical Corpsman. In 1970, he joined FDA as an Investigator at the Indianapolis Resident Post. In 1978, he received a B.S. degree in biology from Indiana University. From 1980 to 1985, he served as Resident-in-Charge at the Sioux Falls Resident Post. In 1985, he was appointed as Supervisory Investigator in the Newark District. He received the FDA Group Recognition Award in 1990 for his efforts regarding the Pony Malta emergency. In 1991, Mr. Graham participated in the Office of Personnel Management's Executive Potential Program. During his program, he received a Special Recognition Award from the Acting Director, Office of Women's Health, Office of the Assistant Secretary for Health, Public Health Service. In 1992, he was appointed as Director, Investigations Branch, Philadelphia District. Mr. Graham assumed his current position in 1994. He is a recipient of Vice President Al Gore's Hammer Award for partnership activities with U.S. Customs on import operations during the 1996 Olympic Games.

JOSEPH R. BACA
Dallas District Director
Food and Drug Administration
Department of Health and Human Services

Joe Baca has been the District Director of the Food and Drug Administration (FDA), Dallas District, since August of 1996. Dallas District is responsible for FDA regulations in the states of Texas, Oklahoma, and Arkansas. Mr. Baca has been with FDA since 1971. Prior to going to Dallas, he was the Compliance Branch Director in the Seattle District from 1987 to 1996; from 1977 to 1987, he was a Compliance Officer in the Minneapolis District; and from 1971 to 1977, he was a Chemist in the Minneapolis District.

He currently serves as the Chairperson of the FDA's Field Food Committee.

Mr. Baca holds a BS degree in Chemistry. His hobbies include bicycling and woodworking.

JoAnn M. Pittman
Public Affairs Specialist
Atlanta District, Office of Regulatory Affairs
Food and Drug Administration
Department of Health and Human Services

Ms. Pittman works with professional and consumer groups in Georgia and South Carolina. She coordinates consumer and health professional education programs, and public participation outreach. She serves as liaison between the FDA and the public. Significant activities include education and outreach programs, consumer inquiries, networking/partnering and managing information. She also acts as a representative of the FDA, appearing on broadcast media and assisting reporters in news story development.

Ms. Pittman is a graduate of Morris Brown College and has over twenty-eight years of work experience with emphasis on consumer service interpersonal skills. Prior to her employment with the FDA, she worked as a legal assistant with the law firm of Najjar, Denaburg of Birmingham, AL, which represented business and commercial litigation, and labor construction law. She worked as a customer service representative with General Motors Corporate office in Birmingham, AL where she promoted customer satisfaction in responding to consumers concerns and complaints on new vehicle purchase and distribution. She taught Business Education courses at Sequoyah High School in Decatur, GA.

She is happily married to James Pittman with children: Jamya, James, and Justin.

The Food and Drug Administration: An Overview



FDA regulates over \$1 trillion worth of products, which account for 25 cents of every dollar spent annually by American consumers.

The Food and Drug Administration touches the lives of virtually every American every day. For it is FDA's job to see that the food we eat is safe and wholesome, the cosmetics we use won't hurt us, the medicines and medical devices we use are safe and effective, and that radiation-emitting products such as microwave ovens won't do us harm. Feed and drugs for pets and farm animals also come under FDA scrutiny. FDA also ensures that all of these products are labeled truthfully with the information that people need to use them properly.

FDA is one of our nation's oldest consumer protection agencies. Its approximately 9,000 employees monitor the manufacture, import, transport, storage and sale of about \$1 trillion worth of products each year. It does that at a cost to the taxpayer of about \$3 per person.

First and foremost, FDA is a public health agency, charged with protecting American consumers by enforcing the Federal Food, Drug, and Cosmetic Act and several related public health laws. To carry out this mandate of consumer protection, FDA has some 1,100 investigators and inspectors who cover the country's almost 95,000 FDA-regulated businesses. These employees are located in district and local offices in 157 cities across the country.

Inspections and Legal Sanctions

These investigators and inspectors visit more than 15,000 facilities a year, seeing that products are made right and labeled truthfully. As part of their inspections, they collect about 80,000 domestic and imported product samples for examination by FDA scientists or for label checks.

If a company is found violating any of the laws that FDA enforces, FDA can encourage the firm to voluntarily correct the problem or to recall a faulty product from the market. A recall is generally the fastest and most effective way to protect the public from an unsafe product.

When a company can't or won't correct a public health problem with one of its products voluntarily, FDA has legal sanctions it can bring to bear. The agency can go to court to force a company to stop selling a product and to have items already produced seized and destroyed. When warranted, criminal penalties--including prison sentences--are sought against manufacturers and distributors.

About 3,000 products a year are found to be unfit for consumers and are withdrawn from the marketplace, either by voluntary recall or by court-ordered seizure. In addition, about 30,000 import shipments a year are detained at the port of entry because the goods appear to be unacceptable.

Scientific Expertise

The scientific evidence needed to back up FDA's legal cases is prepared by the agency's 2,100 scientists, including 900 chemists and 300 microbiologists, who work in 40 laboratories in the Washington, D.C., area and around the country. Some of these scientists analyze samples to see, for example, if products are contaminated with illegal substances. Other scientists review test results submitted by companies seeking agency approval for drugs, vaccines, food additives, coloring agents and medical devices.

FDA also operates the National Center for Toxicological Research at Jefferson, Arkansas, which investigates the biological effects of widely used chemicals. The agency also runs the Engineering and Analytical Center at Winchester, Massachusetts, which tests medical devices, radiation-emitting products, and radioactive drugs.

Assessing risks--and, for drugs and medical devices, weighing risks against benefits--is at the core of FDA's public health protection duties. By ensuring that products and producers meet certain standards, FDA protects consumers and enables them to know what they're buying. For example, the agency requires that drugs--both prescription and over-the-counter--be proven safe and effective.

In deciding whether to approve new drugs, FDA does not itself do research, but rather examines the results of studies done by the manufacturer. The agency must determine that the new drug produces the benefits it's supposed to without causing side effects that would outweigh those benefits.

Product Safety

Another major FDA mission is to protect the safety and wholesomeness of food. The agency's scientists test samples to see if any substances, such as pesticide residues, are present in unacceptable amounts. If contaminants are identified, FDA takes corrective action. FDA also sets labeling standards to help consumers know what is in the foods they buy.

The nation's food supply is protected in yet another way as FDA sees that medicated feeds and other drugs given to animals raised for food are not threatening to the consumer's health.

The safety of the nation's blood supply is another FDA responsibility. The agency's investigators routinely examine blood bank operations, from record-keeping to testing for contaminants. FDA also ensures the purity and effectiveness of biologicals (medical preparations made from living organisms and their products), such as insulin and vaccines.

Medical devices are classified and regulated according to their degree of risk to the public. Devices that are life-supporting, life-sustaining or implanted, such as pacemakers, must receive agency approval before they can be marketed.

FDA's scrutiny does not end when a drug or device is approved for marketing; the agency collects and analyzes tens of thousands of reports each year on drugs and devices after they have been put on the market to monitor for any unexpected adverse reactions.

Cosmetic safety also comes under FDA's jurisdiction. The agency can have unsafe cosmetics removed from the market. The dyes and other additives used in drugs, foods and cosmetics also are subject to FDA scrutiny. The agency must review and approve these chemicals before they can be used.

FDA is an agency within the Public Health Service, which in turn is a part of the Department of Health and Human Services. FDA is headed by Commissioner Jane E. Henney, M.D.

USC United States Code
USDA United States Department of Agriculture
USP United States Pharmacopeia
VAERS Vaccine Adverse Event Reporting System
WEAC Winchester Engineering and Analytical Center

(Hypertext created by clb 1997-SEP-01)

FDA HOME PAGE

Getting Information From FDA



by Dori Stehlin

Each year, thousands of people contact FDA to request information on a gamut of FDA-regulated items, from video display terminals, pet food, and tanning booths to infant formula, the blood supply, and newly approved medical devices, drugs, and biological products.

Exactly what information does FDA have for consumers, and how can they obtain it?

What Does FDA Regulate?

FDA is the federal agency responsible for ensuring that foods are safe, wholesome and sanitary; human and veterinary drugs, biological products, and medical devices are safe and effective; cosmetics are safe; and electronic products that emit radiation are safe. FDA also ensures that these products are honestly, accurately and informatively represented to the public. (For information on what FDA does *not* regulate, see accompanying article.)

Some of the agency's specific responsibilities include:

Biologics:

- product and manufacturing establishment licensing

- safety of the nation's blood supply
- research to establish product standards and develop improved testing methods

Drugs:

- product approvals
- OTC and prescription drug labeling
- drug manufacturing standards

Electronic Products:

- radiation safety performance standards for microwave ovens, television receivers, diagnostic x-ray equipment, cabinet x-ray systems (such as baggage x-rays at airports), laser products, ultrasonic therapy equipment, mercury vapor lamps, and sunlamps
- accrediting and inspecting mammography facilities

Foods:

- labeling
- safety of all food products (except meat and poultry)
- bottled water

Medical Devices:

- premarket approval of new devices
- manufacturing and performance standards
- tracking reports of device malfunctioning and serious adverse reactions

tioning and serious adverse reactions

Veterinary Products:

- livestock feeds
- pet foods
- veterinary drugs and devices

When Does FDA Get Involved?

FDA has legal jurisdiction over products shipped in interstate commerce. A product that is manufactured, shipped and marketed within a state is not, in most cases, subject to FDA regulation. Often, states will adopt guidelines, and they are responsible for ensuring compliance. Consumers with questions or complaints about products that are not involved in interstate commerce should contact their state governments.

Individual states are also responsible for licensing and monitoring the conduct of physicians, pharmacists, and other health-care professionals. State and local governments are also responsible for the inspection and regulation of establishments such as restaurants and health spas.

Public Affairs Specialists

FDA public affairs specialists (PAS's) are located throughout the country and are able to respond to questions about

FDA's programs, policies and procedures. PAS's provide consumers with information that has been prepared for public distribution.

PAS's provide reprints of articles from *FDA Consumer* magazine, brochures, posters, teacher kits, press releases, and background papers on FDA-related topics.

Consumers interested in obtaining audiovisuals can borrow or purchase agency-produced slide shows, videotapes and films. PAS's have information on the available materials, prices, and ordering instructions.

PAS's also speak publicly on topics such as food labeling, health fraud, or AIDS awareness.

To contact the public affairs specialist in your area, look for the Food and Drug Administration entry under the Department of Health and Human Services in the U.S. Government section of your local telephone directory.

Consumer Inquiries Staff

FDA's Consumer Inquiries Staff, located in the agency headquarters offices, is devoted solely to answering consumers' questions. The staff often consult various other FDA offices to find the appropriate answers to consumer inquiries.

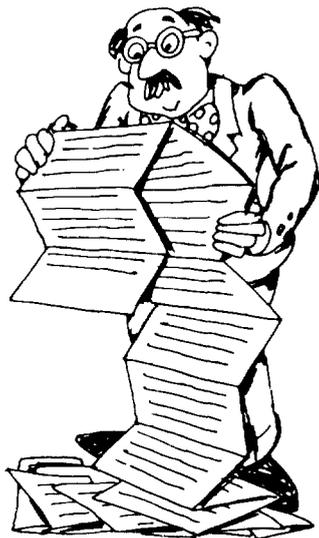
Consumers may request information by writing to the Consumer Inquiries Staff (HFE-88), FDA, 5600 Fishers Lane, Rockville, MD 20857, or may telephone (1-800) 532-4440.

World Wide Web

FDA on the Internet—The FDA Internet Home Page provides up-to-date, authoritative information on food, cosmetics, human and animal drugs, biologics, medical devices, and more.

To access the FDA Home Page, use this URL (uniform resource locator): <http://www.fda.gov/>. From there, you can easily locate consumer education materials, press releases, industry guidance, bulletins for health professionals, and a wealth of other useful documents and data from FDA's centers and offices.

FDA's Internet site replaces the agency's electronic bulletin board, which had provided on-line information for more than a decade. The Internet site



offers far more material, in a more user-friendly form, including easy-to-use full-text searches and hot-links to other FDA documents and other government Internet sites.

FDA Hot Lines for Consumers

Due to increased public interest, FDA has established toll-free hot lines on the following topics:

- *Seafood Hotline* provides information regarding the purchasing, handling and storage of seafood; telephone (800) 332-4010.
- *Vaccine Adverse Event Reporting System* to report any unusual or unexpected adverse reactions associated with the administration of vaccines; telephone (1-800) 822-7967.
- *Mammography Information Service* to find a mammography facility near you that's certified by FDA; telephone (1-800) 332-8615.
- *AIDS Clinical Trials Information Service (ACTIS)* provides information about AIDS and HIV-related trials currently under way in the United States; telephone (1-800) TRIALS-A.

Freedom of Information Staff

Occasionally, consumers seek information that has not been prepared for public dissemination. The Freedom of Information Act ensures public access to most agency documents, including:

- enforcement records, including product recall notifications
- summaries of the basis of approval for new drugs, medical devices, and biologics

- regulatory letters.

The Freedom of Information Act pertains only to existing records and is not a research service that compiles information not already available and identifiable. An FOI request for agency records can be denied only under set guidelines. Documents that may be exempt from the Freedom of Information Act include:

- trade secrets and confidential commercial or financial information
- certain interagency or intra-agency memos or letters
- personnel, medical and similar files that, if released, would constitute an invasion of privacy
- certain records compiled for law enforcement purposes.

All FOI requests must be made in writing and must include the requestor's name, address, and telephone number, as well as a specific statement of the records being sought. Consumers are charged for search time and duplication (with no charge for the first two hours of search time and the first 100 pages of duplication). Search and review time charges range from \$13, \$26, or \$46 per hour, depending on the level of FDA employee filling the request. The photocopying rate is 10 cents per page for standard-size paper or the actual cost per page for odd-size paper. Requests incurring charges of less than \$10 are filled without charge.

For additional information or to make an FOI request, contact the Freedom of Information Staff (HFI-35), FDA, 5600 Fishers Lane, Rockville, MD 20857, or send requests via facsimile to (301) 443-1726.

Our Lips Are Sealed

Many information requests to FDA must be denied due to the confidential nature of the data. FDA employees are prohibited by law from divulging information considered either proprietary or confidential. For example, FDA employees cannot release any information on unapproved drugs unless the manufacturer has given the agency permission or has already released the information to the public. ■

Dori Stehlin is a member of FDA's public affairs staff.

“Sorry, I’ll Have to Refer You to ...”

FDA’s responsibilities are closely related to those of several other government agencies. Often frustrating and confusing for consumers is determining the appropriate regulatory agency to contact. The following contact information is for government agencies that have functions related to that of FDA. (Contact information is given for agency headquarters offices, which are located in the Washington, D.C., area. Local offices, listed in the phone book under U.S. Government, may be available to provide assistance as well.)

Advertising

The Federal Trade Commission is the federal agency which regulates all advertising, excluding prescription drugs and medical devices. FTC ensures that advertisements are truthful and not misleading for consumers. Consumers may write to FTC at 6th St. and Pennsylvania Ave., N.W., Washington, DC 20580; telephone (202) 326-2222.

Alcohol

The labeling and quality of alcoholic beverages are regulated by the Treasury Department’s Bureau of Alcohol, Tobacco, and Firearms. ATF’s address is 650 Massachusetts Ave., N.W., Washington, DC 20226; telephone (202) 927-7777.

Consumer Products

While FDA regulates a large portion of the products that consumers purchase, the agency has no jurisdiction over many household goods. The Consumer Product

Safety Commission (CPSC) is responsible for ensuring the safety of consumer goods such as household appliances (excluding those that emit radiation), paint, child-resistant packages, and baby toys. Consumers may send written inquiries to CPSC, Washington, DC 20207. CPSC operates a toll-free hot line at (800) 638-2772 or TTY (800) 638-8270 for consumers to report unsafe products or to obtain information regarding products and recalls.

Drugs of Abuse

Illegal drugs with no approved medical use—such as heroin, cocaine and marijuana—are under the jurisdiction of the Drug Enforcement Agency (DEA). FDA assists DEA in deciding how stringent DEA controls should be on drugs that *are* medically accepted but that have a strong potential for abuse. DEA establishes limits on the amount of these prescription drugs that are permitted to be manufactured each year. Inquiries regarding DEA activities may be sent to the Drug Enforcement Administration, U.S. Department of Justice, Washington, DC 20537; telephone (202) 307-1000.

Meat and Poultry

The U.S. Department of Agriculture’s Food Safety and Inspection Service is responsible for the safety and labeling of traditional meats and poultry. (FDA regulates game meats, such as venison, ostrich and snake.) Consumers with questions regarding meat or poultry, including safe handling and storage

practices, should write or call the Food Safety Inspection Service’s Meat and Poultry Hotline, Room 2925S, Washington, DC 20250; telephone (800) 535-4555.

Pesticides

FDA, USDA, and the Environmental Protection Agency share the responsibility for regulating pesticides. EPA determines the safety and effectiveness of the chemicals and establishes tolerance levels for residues on feed crops, as well as for raw and processed foods. These tolerance levels (the amount of pesticide allowed to be present in a food product) are normally set 100 times below the level that might cause harm to people or the environment. FDA and USDA are responsible for monitoring the food supply to ensure that pesticide residues do not exceed the allowable levels in the products under their jurisdiction. Public inquiries regarding EPA should be mailed to U.S. Environmental Protection Agency, Office of Pesticide Programs Public Docket (7506C), 3404, 401 M St., Washington, DC 20460; telephone (202) 260-2080.

Restaurants and Grocery Stores

Inspections and licensing of restaurants and grocery stores are typically handled by local county health departments.

Water

The regulation of water is divided between EPA and FDA. EPA has the responsibility for developing national standards for drinking water from municipal water supplies. FDA regulates the labeling and safety of bottled water. ■

**A REPRINT FROM
FDA CONSUMER MAGAZINE**

Printed December 1996.
This reprint contains revisions made
in December 1996.
This article originally appeared in the
December 1990 *FDA Consumer*.

PUBLICATION NO. (FDA) 97-1167

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service Food and Drug Administration
FDA on the Internet: <http://www.fda.gov/>

We hope you found this reprint from *FDA Consumer* magazine useful and informative. *FDA Consumer*, the magazine of the U.S. Food and Drug Administration, provides a wealth of information on FDA-related health issues: food safety, nutrition, drugs, medical devices, cosmetics, radiation protection, vaccines, blood products, and veterinary medicine. For a sample copy of *FDA Consumer* and a subscription order form, write to: Food and Drug Administration, HFI-40, Rockville, MD 20857.

☆ U.S. GOVERNMENT PRINTING OFFICE 1997-417-597/40043

U.S. Food and Drug Administration

FDA-Related Acronyms and Abbreviations

510(k)	Medical Device Premarket Notification
AADA	Abbreviated Antibiotic Drug Application
ADR	Adverse Drug Reaction
AFDO	Association of Food and/Drug Officials
ANADA	Abbreviated New Animal Drug Application
ANDA	Abbreviated New Drug Application
AOAC	Association of Official Analytical Chemists
APHIS	Animal and Plant Health Inspection Service
ATF	Alcohol, Tobacco, and Firearms (Bureau of)
CANDA	Computer Assisted New Drug Application
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
CFSAN	Center for Food Safety and Applied Nutrition
CSI	Consumer Safety Inspector
CSO	Consumer Safety Officer
CVM	Center for Veterinary Medicine
DAL	Defect Action Level
DD	District Director
DEA	Drug Enforcement Administration
DESI	Drug Efficacy Study Implementation
DHHS	Department of Health and Human Services
EPA	Environmental Protection Agency
FDC	Food, Drug, & Cosmetic
FOIA	Freedom of Information Act
FR	Federal Register
FSIS	Food Safety and Inspection Service
FTE	Full Time Equivalent (employee)
FTC	Federal Trade Commission
FY	Fiscal Year
GATT	General Agreement on Tariffs and Trade
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe (food ingredients)



HACCP	Hazard Analysis Critical Control Point (inspection technique)
IDE	Investigational Device Exemption
INADA	Investigational New Animal Drug Application
IND	Investigational New Drug (application)
IRB	Institutional Review Board
LACF	Low Acid Canned Food
MOD 1	Module One (laboratory facility)
MOD 2	Module Two (laboratory facility)
MOU	Memorandum of Understanding
MQSA	Mammography Quality Standards Act of 1992
NADA	New Animal Drug Application
NAFTA	North American Free Trade Agreement
NCE	New Chemical Entity
NCI	National Cancer Institute
NCTR	National Center for Toxicological Research
NDA	New Drug Application
NIH	National Institutes of Health
NLEA	Nutrition Labeling and Education Act of 1990
NME	New Molecular Entity
NMFS	National Marine Fisheries Service
OC	Office of the Commissioner
OCA	Office of Consumer Affairs
OCI	Office of Criminal Investigation
OEI	Official Establishment Inventory
OHA	Office of Health Affairs
OLA	Office of Legislative Affairs
OPA	Office of Public Affairs
OPE	Office of Planning and Evaluation
ORA	Office of Regulatory Affairs
OTC	Over-the-Counter (drugs)
PAS	Public Affairs Specialist
PDMA	Prescription Drug Marketing Act
PDP	Product Development Protocols (for medical devices)
PHS	Public Health Service
PLA	Product License Application (for biologics)
PMA	Pre-Market Approval (application) (for medical devices)
RFDD	Regional Food and Drug Director
SBA	Summary Basis of Approval
SMDA	Safe Medical Devices Act

USC United States Code
USDA United States Department of Agriculture
USP United States Pharmacopeia
VAERS Vaccine Adverse Event Reporting System
WEAC Winchester Engineering and Analytical Center

(Hypertext created by clb 1997-SEP-01)

[FDA HOME PAGE](#)

Resources on the World Wide Web

U.S. Food and Drug Administration Home Page
www.fda.gov

Office of Special Health Issues Home Page
www.fda.gov/oashi/home.html

FDA Cancer Liaison Program Home Page
www.fda.gov/oashi/cancer/cancer.html

Oncology Patient Representative Nomination Letter
www.fda.gov/oashi/cancer/cpatlr.html

When a Patient Speaks... Patient Representatives to FDA Advisory Committees
www.fda.gov/oashi/patrep/patbroc.html

Thalidomide Patient Brochure
www.fda.gov/cder/news/thalidomide.htm

From Test Tube to Patient: Drug Development in the United States
www.fda.gov/fdac/special/newdrug/ndd_toc.html

The FDA Modernization Act of 1997 backgrounder
www.fda.gov/opacom/backgrounders/modact.htm

FDA Modernization Act of 1997
HTML format: www.fda.gov/cder/guidance/105-115.htm
PDF format: www.fda.gov/cder/guidance/s830enr.pdf

AIDS Clinical Trial Information Service (ACTIS)
www.actis.org

NCI PDQ Database
cancernet.nci.nih.gov/pdq.htm

Cancer Clinical Trials Database
cancertrials.nci.nih.gov

FDA Office of Orphan Products Development
www.fda.gov/orphan

Rare Diseases Clinical Research Database
rarediseases.info.nih.gov/ord/wwwprot/index.shtml

For more information, please contact:
Food and Drug Administration, Office of Special Health Issues
5600 Fishers Lane, Room 9-49, HF-12
Rockville, MD 20857 • Office: 301-827-4460 • Email: oshi@oc.fda.gov

**U. S. FOOD AND DRUG ADMINISTRATION
RESOURCE SHEET
Medical Product Reporting Programs**

MedWatch (24 hour service) -----	1-800-332-1088
<i>Reporting of problems with drugs, devices, biologics (except vaccines, medical foods, dietary supplements).</i>	
Vaccine Adverse Event Reporting (24 hour service) -----	1-800-822-7967
<i>Reporting of vaccine-related problems.</i>	
Mandatory Medical Device Reporting -----	301-594-3886
<i>Reporting required from user facilities regarding device-related deaths & serious injuries.</i>	
Veterinary Adverse Drug Reaction Program -----	1-888-FDA-VETS
<i>Reporting of adverse drug events in animals. (Call collect during business hours).</i>	
Medical Advertising -----	1-800-238-7332
<i>Inquiries from health professionals regarding product promotion.</i>	
USP Medication Errors -----	1-800-233-7767
<i>Reporting of medication errors or near-errors to help avoid future problems through improvement on Product names and packaging.</i>	

Information for Health Professionals

Center for Drugs Information Branch -----	301-827-4573
<i>Information on human drugs including hormonal products.</i>	
Center for Biologics Executive Secretariat -----	301-827-2000
<i>Information on biological products including vaccines and blood</i>	
	1-800-835-4709
Center for Devices and Radiological Health -----	301-443-4109
<i>Automated request for information on devices and radiation-emitting products.</i>	
Office of Orphan Products Development -----	301-827-3666
<i>Information on products for rare diseases.</i>	
Office of Health Affairs, Medicine Staff -----	301-827-6630
<i>Information for health professionals on FDA activities.</i>	

General Information

General Consumer Inquiries -----	1-888-463-6332
<i>Consumer information on regulated products/issues.</i>	
Freedom of Information -----	301-827-6567
<i>Requests for publicly available FDA documents.</i>	
Office of Public Affairs -----	301-827-6250
<i>Interviews/press inquiries on FDA activities.</i>	
Seafood Hotline (24 hour service) -----	1-800-332-4010
<i>Prerecorded message/request information (English/Spanish).</i>	

U.S. Food and Drug Administration

Text Version for Browsers that do not support tables

FDA Backgrounders

Title	Backgrounder #	Date Issued
<u>Food Safety: A Team Approach</u>	BG 98-7	September 24, 1998
<u>Making Your Voice Heard at FDA: How to Comment on Proposed Regulations and Submit Petitions</u>	BG 98-6	September 15, 1998
<u>How to Report Adverse Reactions and Other Problems with Products Regulated by FDA</u>	BG 99-1	January 1, 1999
<u>Summary of U.S. Court of Appeals for the Fourth Circuit Ruling on FDA's Jurisdiction Over, and Regulation of, Cigarettes and Smokeless Tobacco</u>	BG 98-4	Aug. 21, 1998
<u>A Handbook for Requesting Information and Records from FDA</u>	BG 98-2	April 1, 1998
<u>The FDA Modernization Act of 1997</u>	BG 97-13	November 21, 1997
<u>HACCP: State-of-the-Art Approach to Food Safety</u>	BG 97-11	August 12, 1997
<u>Alpha Hydroxy Acids in Cosmetics</u>	BG 97-10	July 3, 1997
<u>Summary of Federal District Court's Ruling on FDA's Jurisdiction Over, and Regulation of, Cigarettes and Smokeless Tobacco</u>	BG 97-9	May 2, 1997
<u>The New Federal Tobacco Rule: A Retailer's Guide to the Age and ID Requirements</u>	BG 97-2	January 25, 1997
<u>Preventing Iron Poisoning in Children</u>	BG 97-1	January 15, 1997
<u>Top Health Frauds</u>	BG 96-8	November 6, 1996
<u>Fact Sheet on Xenotransplantation</u>	BG 96-6	September 20, 1996
<u>Home-Use HIV Test Kits</u>	BG 96-5	May 14, 1996
<u>FDA: A Record of Accomplishment</u>	BG 96-4	May 1, 1996
<u>Cancer Therapies: Accelerating Approval and Expanding Access</u>	BG 96-3	March 29, 1996
<u>FDA Food Code</u>	BG 99-3	April 8, 1999
<u>Olestra and Other Fat Substitutes</u>	BG 95-18	November 28, 1995
<u>Monosodium Glutamate</u>	BG 95-16	August 31, 1995
<u>Milestones in U.S. Food and Drug Law History</u>	BG 95-15	August 30, 1995
<u>The New Food Label</u>	BG 95-14	May 1995

<u>FDA: An Overview</u>	BG 99-2	January 11, 1999
<u>FDA Mission: Protect Public Health</u>	BG 95-10	March 30, 1995
<u>Biotechnology of Food</u>	BG 94-4	May 1994
<u>BST: New Animal Drug for Increasing Milk Production</u>	BG 93-3	November 18, 1993
<u>User Fees</u>	BG 93-2	July 1993
<u>Safe Use of Physical Restraint Devices</u>	BG 92-3	July 1992
<u>Imports and FDA</u>	BG 92-2	May 18, 1992
<u>Reducing Exposure to Lead from Ceramic Ware</u>	BG 91-8.2	November 1991
<u>Collagen and Liquid Silicone Injections</u>	BG 91-5.1	August 1991
<u>When Consumers Report Product-Related Problems to FDA</u>	BG 91-2.0	March 1991
<u>Seafood Safety</u>	BG 90-3.2	May 1991
<u>Color Additives</u>	none	February 1990

FDA HOME PAGE

(Hypertext updated by srl 1999-APR-20)



How to Report Adverse Reactions and Other Problems With Products Regulated by FDA

Consumers can play an important public health role by reporting to the U.S. Food and Drug Administration any adverse reactions or other problems with products the agency regulates. FDA is responsible for ensuring that foods are safe, wholesome, and correctly labeled. It also oversees medicines, medical devices (from bandages to artificial hearts), blood products, vaccines, cosmetics, veterinary drugs, animal feed, and electronic products that emit radiation (such as microwave ovens and video monitors), ensuring that these products are safe and effective.

The testing that helps to establish the safety of products, such as drugs and medical devices, is typically conducted on small groups before FDA approves the products for sale. Some problems can remain unknown, only to be discovered when a product is used by a large number of people.

When problems with FDA-regulated products occur, the agency wants to know about them and has several ways for the public to make reports. Timely reporting by consumers, health professionals, and FDA-regulated companies allows the agency to take prompt action. The agency evaluates each report to determine how serious the problem is, and, if necessary, may request additional information from the person who filed the report before taking action.

Reporting an Emergency

If the situation is an emergency that requires immediate action, such as a case of food-borne illness or a drug product that has been tampered with, call the agency's main emergency number, staffed 24 hours a day, 301-443-1240.

You also can report emergencies to an FDA consumer complaint coordinator in your geographic area. A list of all the coordinators' phone numbers is on page 3.

Non-Emergency Reports

If you experience a problem that does not require immediate action—such as a non-emergency adverse reaction to a food product or an over-the-counter medical device that doesn't work as advertised—you can report it to the appropriate consumer complaint coordinator. (See list of coordinators on page 3.) Or you can report it to the appropriate FDA office from the following list:

Foods

- To report problems, including adverse reactions, related to any food except meat and poultry, contact the complaint coordinator in your geographic area. (See list of coordinators on page 3.)
- If the problem involves meat or poultry, which are regulated by the U.S. Department of Agriculture, call the USDA hotline at 1-800-535-4555.

Medicines (prescription and over-the-counter), medical devices, blood products and other biologicals, special nutritional products (dietary supplements, infant formula, medical foods)

FDA's MedWatch program is designed for health professional and consumer reporting of **serious** adverse events and problems with medical products, so that these events and problems can be monitored. An adverse event is considered serious if the outcome attributed to the event is: death; a life-threatening situation; admission to a hospital or a longer-than-expected hospital stay; permanent disability; a birth defect; or medical/surgical care to prevent permanent impairment or damage.

In addition, MedWatch works to ensure that new safety information is quickly communicated to the health professional community. The program aims to enhance postmarketing surveillance of medical products as they are used in clinical practice, so that FDA can, as rapidly as possible, identify

serious reactions and hazards associated with these products. To report a problem to MedWatch:

- If you or a family member has experienced or witnessed a serious adverse event or other problem with a medical product, you can obtain a MedWatch form by:
 - Calling MedWatch at 1-800-FDA-1088 (1-800-332-1088) to request that a reporting form (one-page, return postage paid) and instructions on how to complete the form be mailed to you.
 - Downloading a form and instructions from the MedWatch Website at <http://www.fda.gov/medwatch/how.htm>. Completed forms can be mailed to FDA at the address on the back of the form or faxed to 1-800-FDA-0178 (1-800-332-0178).
 - You can also report directly to FDA by using the interactive form available on the MedWatch Website at <https://www.accessdata.fda.gov/medwatch/medwatch-online.htm>.
- FDA encourages consumers to take the form to their health professional (doctor, dentist, pharmacist, or nurse) to complete. This person can provide much more detailed clinical information, such as laboratory results, which can help FDA evaluate the report. Since reporting by health professionals is voluntary, consumers are encouraged to file a report on their own if they prefer that a health professional not fill out the form or if the health professional chooses not to report the problem.
- FDA also welcomes reports through MedWatch of product quality problems. For example, you can report product contamination (suspicious foul odors or unusual "off" colors); defective components; labeling concerns (such as mix-ups due to similar names or packaging); or questionable product stability.

Vaccines

Adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting System, which is maintained by FDA and the Centers for Disease Control and Prevention. For a copy of the vaccine reporting form, call 1-800-822-7967 or on the FDA website at <http://www.fda.gov/cber/vaers.html>.

Veterinary Products

Report any problems with veterinary drugs and animal feed to FDA's Center for Veterinary Medicine at 1-888-FDA-VETS (1-888-332-8387).

Cosmetics

Call the FDA Cosmetics and Colors Automated Information Line 1-800-270-8869, for information on how to report adverse reactions to cosmetics, as well as problems such as filth, decomposition, or spoilage.

Medical Advertising

To report fraudulent or misleading advertising or promotion of FDA-regulated products, call 1-800-238-7332.

General Guidelines About Reporting

- Report what happened as soon as possible. Give names, addresses and phone numbers of persons affected. Include your name, address and phone number, as well as that of the doctor or hospital if emergency treatment was provided.
- State the problem clearly. Describe the product as completely as possible, including any codes or identifying marks on the label or container. Give the name and address of the store where the product was purchased and the date of purchase.
- You also should report the problem to the manufacturer or distributor shown on the label and to the store where you purchased the product.

What FDA Doesn't Handle

Reports and complaints about the following should be made to the agencies listed. Phone numbers can be found in your local phone directory:

- Restaurant food and sanitation—Local or state health departments
- Unsolicited products in the mail—U.S. Postal Service
- Accidental poisonings—Poison control centers or hospitals
- Pesticides or air and water pollution—U.S. Environmental Protection Agency
- Hazardous household products (including toys, appliances, and chemicals)—Consumer Product Safety Commission, 1-800-638-2772

FDA Consumer

The Magazine of the U.S. Food and Drug Administration

VOL. 33 NO. 3

MAY-JUNE 1999

Features

Waging War on Lung Cancer

Though lung tumors kill more people than any other cancer, survival rates have improved, and new tools are helping doctors find the disease when treatment has the best chance for success.

New Vaccine Targets Lyme Disease

A new vaccine and improved screening tests may curb the rising numbers of Lyme infections. But simple precautions are still necessary.

Dental More Gentle with Painless 'Drillings' and Matching Fillings

"Ouchless" lasers and color-coordinated ceramics are helping lighten up a visit to the dentist.

Pediatric Drug Studies: Protecting Pint-Sized Patients

More than half of the prescription drugs that children are likely to use have not been adequately tested or labeled for youngsters. But an FDA rule now requires makers of many drugs to provide information on safe pediatric use.

Orphan Drug Law Matures into Medical Mainstay

In 1983, Congress passed a law to help bring treatments to people suffering from rare, or "orphan," disorders. The result is a growing list that currently includes nearly 200 drugs and other products.

Departments

Updates

The latest information on FDA-related issues, gathered from FDA Press Releases, Talk Papers, and other sources.

Investigators' Reports

Selected cases illustrating regulatory and administrative actions--such as inspections, recalls, seizures, and court proceedings--by FDA's regional and district offices across the country

For more information about FDA Consumer magazine, contact FDA's Office of Public Affairs at 301-827-7130 or wmail@oc.fda.gov.

**U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition**

Information about Dietary Supplements

Information from the Center for Food Safety and Applied Nutrition and FDA

- FDA Warns About Products Containing Gamma Butyrolactone or GBL and Asks Companies to Issue a Recall (FDA Talk Paper, January 21, 1999)
- Impurities Confirmed in 5-Hydroxy-L-Tryptophan (5HTP) (FDA Talk Paper, September 1, 1998)
- FDA Warns Consumers Against Taking Dietary Supplement "Sleeping Buddha" (FDA Statement, March 10, 1998)
- FDA Warns Against Drug Promotion of "Herbal Fen-Phen" (FDA Talk Paper, November 6, 1997)
- FDA Warns Consumers Against Dietary Supplement Products That May Contain Digitalis Mislabeled as "Plaintain" (HHS News, June 12, 1997; Updated Again July 2, 1997 / Additional firms listed)
- FDA Warns Against Consuming the Arise & Shine Product "CHOMPER" (HHS News, May 16, 1997)

- Overview
- An FDA Guide to Dietary Supplements September 1998
- Health Claims on Foods
- Products Consumers Inquire About
- The Special Nutritionals Adverse Event Monitoring System
- Statement by FDA Commissioner before the House of Representatives March 25, 1999

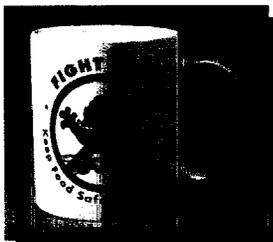
- Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific Body
- FDA Proposes Rules to Make Claims for Dietary Supplements More Informative, Reliable and Uniform (April 24, 1998)
 - FDA's Response to the Report of the Commission on Dietary Supplement Labels
 - Fact Sheet, April 27, 1998
 - Federal Register, April 29, 1998
 - FDA's Dietary Supplement Proposal
 - Fact Sheet, April 27, 1998
 - Federal Register, April 29, 1998

- Dietary Supplement Health and Education Act Summary
- Dietary Supplement Rules Proposed (January 2, 1996 Talk Paper)
- February 6, 1997 ANPR: Current Good Manufacturing Practice in Manufacturing, Packaging and Holding of Dietary Supplements
- June 4, 1997 Proposed Rule: Dietary Supplements Containing Ephedrine Alkaloids
- Dietary Supplement Rules Published (September 23, 1997 Talk Paper)

- September 23, 1997 Final Rule Food Labeling; Statement of Identity, Nutrition Labeling and Ingredient Labeling of Dietary Supplements; Compliance Policy Guide, Revocation
- September 23, 1997 Final Rule Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements
- September 23, 1997 Final Rule Food Labeling; Nutrient Content Claims: Definition for "High Potency" and Definition of "Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and Conventional Foods
- September 23, 1997 Final Rule Food Labeling; Notification Procedures for Statements on Dietary Supplements
- September 23, 1997 Final Rule Premarket Notification for a New Dietary Ingredient
- Statement of Identity, Nutrition Labeling, and Ingredient Labeling of Dietary Supplements Small Entity Compliance Guide January 1999
- Codex Committee on Nutrition and Foods for Special Dietary Uses
 - Information Paper on Codex Proposed Guidelines
 - Risk Assessment Model for Establishing Upper Intake Levels for Nutrients
 - Abridged Version
 - Full Paper (117 KB compressed, self-extracting, MS Word document)

Information from Other Federal Government Agencies

- National Institutes of Health, Office of Dietary Supplements
 - International Bibliographic Information on Dietary Supplements



A. CERAMIC MUG

11-ounce white ceramic mug with four-color Fight BAC!™ logo on two sides.
Price: \$8.00 each.



B. APRON

21" white, pocketed, tie-back apron with four-color Fight BAC!™ logo.
Price \$10.00 each.



C. EMBLEMS

1" embroidered, removable appliqué with four-color Fight BAC!™ logo.
Price: \$1.25 each (10 minimum)



D. MAGNETS

3" x 4" four-color magnet with the four quadrants encompassing the Fight BAC!™ logo.
Price: \$.75 each (25 minimum)

Visit our website for publication materials including Fight BAC!™ English and Spanish brochures, Community Action Kits, Presenter's Guides and more. To order, see "Spread the Word" icon at www.fightbac.org online.



E. STICKERS

2" diameter four-color sticker with Fight BAC!™ logo.
Price: \$50.00 per roll of 500. (1 Roll)



F. BOOKMARKS

7.5" x 2.5" four-color bookmark with Fight BAC!™ logo and safe food handling instructions (thermometer). Both sides printed.
Price: \$.75 each. (10 minimum)



G. POSTERS

19" x 27" four-color varnished poster with the four quadrants encompassing the Fight BAC!™ logo.
Price: \$1.00 each (10 minimum)

The Partnership
for
Food Safety Education



FIGHT BAC!TM
STORE
1999

FIGHT BAC!™ ORDERING INSTRUCTIONS

General Information

Telephone Numbers

API/BAC™ Store
9:00 a.m. to 5:00 p.m. ET
Phone (301)731-6100
Fax (301)731-6101

Mailing Address

API/BAC™ Store
4550 Forbes Blvd. Suite 120
Lanham, MD 20706

Payment Terms

Prepayment by check payable to API or charge to your MasterCard or Visa. When purchasing by credit card, your telephone number and signature must be provided. Shipping & handling charges must be added to all orders.

Delivery

Orders for all stocked items will be shipped within 3 weeks of receipt of order.

Ordering and Customer Service

Placing Your Order: Fill out a copy of the order form, being sure to note minimum quantity requirements.

Please type or print clearly for accurate processing of your order. All orders will be given immediate attention. If we have a question when we receive your order, our Customer Service Department will call you to clarify your request. All prices are subject to change without prior notification. For larger quantity orders, please contact our Customer Service Department at (301)731-6100.

Publication Materials: To order today, please visit our online store at www.fightbac.org under "Spread the Word" (icon).

Returns: Return any item and we will replace it or issue a credit if returned within 2 weeks from receipt of order.

Fill out the back of the packing slip included with your shipment and return it to the address on the packing slip within two weeks. This packing slip gives all the information we need for prompt replacement or credit. If you return an item without the packing slip, it will create delays. Please ship your returns via a method that can be traced.

Damages: If your order is damaged in transit please call our Customer Service Department at (301)731-6100 for instructions.

Thank you for joining the Fight BAC!™ Campaign!



ORDER FORM API/FIGHT BAC!™

4550 Forbes Blvd • Lanham, MD 20706

Order Date ____ / ____ / ____

Use copy of this form to fax, mail or call in your order.

If mailing, send a copy of form and retain original for reference.

Company/Organization: _____
Contact Name: _____
Street: _____
City/State/Zip: _____
Telephone/Fax Number: _____
Telephone number MUST be included on all orders
(Please type or print clearly for accurate processing of your order)

METHOD OF PAYMENT

Charge to my: _____
 VISA Enclosed check in the amount of _____
 MASTERCARD
 Cardholder Name: _____
 Card Number: _____ Exp.: ____ / ____
 Signature: _____

Item No.	Qty.	Description	Price Each	Total Price
A	(A)	Ceramic Mug	\$8.00	
B	(B)	Apron	\$10.00	
C	(C)	Emblems (10 min.)	\$1.25	
D	(D)	Magnets (25 min.)	\$.75	
E	(E)	Stickers (1 roll min.)	\$50.00	
F	(F)	Bookmarks (10 min.)	\$.75	
G	(G)	Posters (10 min.)	\$1.00	

Order by phone:
(301) 731-6100
fax:
(301) 731-6101
or online:
www.fightbac.org

Total Merchandise Cost	
Rush	
Shipping & Handling	
Sub Total	
MD/DC/VA Sales Tax	
Total	

Shipping & Handling

Include the following amounts for shipping and handling for standard shipments: (shipping and handling charges must be added to all orders.)

\$ 00.01 to \$ 10.00	add \$ 4.95
\$ 10.01 to \$ 25.00	add \$ 5.95
\$ 25.01 to \$ 50.00	add \$ 6.95
\$ 50.01 to \$ 100.00	add \$ 8.95
\$ 100.01 to \$ 200.00	add \$ 14.95
\$ 200.00 and above	add \$ 4.95 plus 6% of order.

Note: All rush orders and shipments outside of the continental U.S. will require a handling charge of \$10.00 plus the actual freight charge.

**B A C K G R O U N D E R**

CURRENT & USEFUL INFORMATION FROM THE FOOD & DRUG ADMINISTRATION

Food Safety: A Team Approach

September 24, 1998

The United States maintains one of the world's safest food supplies, thanks in large part to an interlocking monitoring system that watches over food production and distribution at every level-locally, statewide and nationally.

Continual monitoring is provided by food inspectors, microbiologists, epidemiologists, and other food scientists working for city and county health departments, state public health agencies, and various federal departments and agencies. Their precise duties are dictated by local, state and national laws, guidelines and other directives. Some monitor only one kind of food, such as milk or seafood. Others work strictly within a specified geographic area. Others are responsible for only one type of food establishment, such as restaurants or meat-packing plants. Together they make up the U.S. food safety team.

The Clinton administration's Food Safety Initiative, begun in 1997, strengthens the efforts of all the members of the nation's food safety team in the fight against food-borne illness, which afflicts between 6.5 million and 33 million Americans every year. One of the initiative's major programs got under way in May 1998 when the Department of Health and Human Services (which includes FDA), the U.S. Department of Agriculture, and the Environmental Protection Agency signed a memorandum of understanding to create a Food Outbreak Response Coordinating Group, or FORC-G. The new group will:

- increase coordination and communication among federal, state and local food safety agencies
- guide efficient use of resources and expertise during an outbreak
- prepare for new and emerging threats to the U.S. food supply.

Besides federal officials, members of FORC-G include the Association of Food and Drug Officials, National Association of City and County Health Officials, Association of State and Territorial Public Health Laboratory Directors, Council of State and Territorial Epidemiologists, and National Association of State Departments of Agriculture.

The following table offers a closer look at the nation's food safety lineup. The agencies listed in the table also work with other government agencies, such as the Consumer Product Safety Commission to enforce the Poison Prevention Packaging Act, the FBI to enforce the Federal Anti-Tampering Act, the Department of Transportation to enforce the Sanitary Food Transportation Act, and the U.S. Postal Service to enforce laws against mail fraud.

U.S. Department of Health and Human Services *

Food and Drug Administration

Oversees

- All domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry
- Bottled water
- Wine beverages with less than 7 percent alcohol

Food Safety Role

Enforces food safety laws governing domestic and imported food, except meat and poultry, by:

- Inspecting food production establishments and food warehouses and collecting and analyzing samples for physical, chemical and microbial contamination
- Reviewing safety of food and color additives before marketing
- Reviewing animal drugs for safety to animals that receive them and humans who eat food produced from the animals
- Monitoring safety of animal feeds used in food-producing animals
- Developing model codes and ordinances, guidelines and interpretations and working with states to implement them in regulating milk and shellfish and retail food establishments, such as restaurants and grocery stores. An example is the model Food Code, a reference for retail outlets and nursing homes and other institutions on how to prepare food to prevent food-borne illness.
- Establishing good food manufacturing practices and other production standards, such as plant sanitation, packaging requirements, and Hazard Analysis and Critical Control Point programs
- Working with foreign governments to ensure safety of certain imported food products
- Requesting manufacturers to recall unsafe food products and monitoring those recalls
- Taking appropriate enforcement actions
- Conducting research on food safety
- Educating industry and consumers on safe food handling practices

For More Information

Consumers:

FDA Headquarters

Office of Consumer Affairs

HFE-88

5600 Fishers Lane

Rockville, MD 20857

Regional FDA offices, listed in the blue pages of the phone book under U.S. Government

Media inquiries: 202-205-4144

Consumers:

FDA's Food Information and Seafood Hotline

1-800-FDA-4010 (1-800-332-4010),

202-205-4314 in the Washington, D.C., area

www.cfsan.fda.gov/list.html

www.fda.gov/cvm/

Centers for Disease Control and Prevention

Oversees

- All foods

Food Safety Role

- Investigates with local, state and other federal officials sources of food-borne disease outbreaks
- Maintains a nationwide system of food-borne disease surveillance: Designs and puts in place rapid, electronic systems for reporting food-borne infections. Works with other federal and state agencies to monitor rates of and trends in food-borne disease outbreaks. Develops state-of-the-art techniques for rapid identification of food-borne pathogens at the state and local levels.
- Develops and advocates public health policies to prevent food-borne diseases
- Conducts research to help prevent food-borne illness
- Trains local and state food safety personnel

For More Information

Centers for Disease Control and Prevention
1600 Clifton Rd., N.E.
Atlanta, GA 30333

Media inquiries: 404-639-3286

General public: 404-639-3311

www.cdc.gov

* Also, HHS's National Institutes of Health conduct food safety research.

U.S. Department of Agriculture **

Food Safety and Inspection Service

Oversees

- Domestic and imported meat and poultry and related products, such as meat- or poultry-containing stews, pizzas and frozen foods
- Processed egg products (generally liquid, frozen and dried pasteurized egg products)

Food Safety Role

Enforces food safety laws governing domestic and imported meat and poultry products by:

- Inspecting food animals for diseases before and after slaughter
- Inspecting meat and poultry slaughter and processing plants
- With USDA's Agricultural Marketing Service, monitoring and inspecting processed egg products
- Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, plant sanitation, thermal processing, and other processes
- Making sure all foreign meat and poultry processing plants exporting to the United States meet U.S. standards
- Seeking voluntary recalls by meat and poultry processors of unsafe products
- Sponsoring research on meat and poultry safety
- Educating industry and consumers on safe food-handling practices

For More Information

FSIS Food Safety Education and Communications Staff
Room 1175, South Building,
1400 Independence Ave., S.W.
Washington, DC 20250

Media inquiries: 202-720-9113

Consumers:
The Meat and Poultry Hotline, 1-800-535-4555
(In Washington, D.C., area, call 202-720-3333.)
TDD/TTY: 1-800-256-7072

www.fsis.usda.gov

Cooperative State Research, Education, and Extension Service

Oversees

- All domestic foods, some imported

Food Safety Role

- With U.S. colleges and universities, develops research and education programs on food safety for farmers and consumers

For More Information

Local cooperative extension services, listed in the blue pages of the phone book under county government

Cooperative State Research, Education and Extension Service
U.S. Department of Agriculture
Washington, DC 20250-0900
202-720-3029

www.reeusda.gov

National Agricultural Library USDA/FDA Foodborne Illness Education Information Center

Oversees

- All foods

Food Safety Role

- Maintains a database of computer software, audiovisuals, posters, games, teachers' guides and other educational materials on preventing food-borne illness
- Helps educators, food service trainers and consumers locate educational materials on preventing food-borne illness

For More Information

USDA/FDA Foodborne Illness Education Information Center
Food and Nutrition Information Center
National Agricultural Library/USDA
Beltsville, MD 20705-2351

301-504-5719

www.nal.usda.gov/fnic/

** Also, a number of other USDA agencies conduct food safety activities.

U.S. Environmental Protection Agency

Oversees

- Drinking water

Food Safety Role

Foods made from plants, seafood, meat and poultry

- Establishes safe drinking water standards
- Regulates toxic substances and wastes to prevent their entry into the environment and food chain
- Assists states in monitoring quality of drinking water and finding ways to prevent

contamination of drinking water

- Determines safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on safe use of pesticides

For More Information

Environmental Protection Agency
401 M St., S.W.
Washington, DC 20460

202-260-2090

Regional EPA offices, listed in the blue pages of the phone book under U.S. Government

www.epa.gov

U.S. Department of Commerce

National Oceanic and Atmospheric Administration

Oversees

- Fish and seafood products

Food Safety Role

- Through its fee-for-service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards

For More Information

Seafood Inspection Program
1315 East-West Highway
Silver Spring, MD 20910

1-800-422-2750

www.nmfs.gov/iss/services.html

U.S. Department of the Treasury

Bureau of Alcohol, Tobacco and Firearms

Oversees

- Alcoholic beverages except wine beverages containing less than 7 percent alcohol

Food Safety Role

- Enforces food safety laws governing production and distribution of alcoholic beverages

- Investigates cases of adulterated alcoholic products, sometimes with help from FDA

For More Information

Bureau of Alcohol, Tobacco and Firearms
Market Compliance Branch
650 Massachusetts Ave., N.W.
Room 5200
Washington, DC 20226

202-927-8130

www.atf.treas.gov/core/alcohol/alcohol.htm

U.S. Customs Service

Oversees

- Imported foods

Food Safety Role

- Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations

For More Information

U.S. Customs Service
P.O. Box 7407
Washington, DC 20044

Media inquiries: 202-927-1770

General public: Contact local ports of entry, listed in the blue pages of the phone book under U.S. Government, Customs Services

www.customs.ustreas.gov

U.S. Department of Justice

Oversees

- All foods

Food Safety Role

- Prosecutes companies and individuals suspected of violating food safety laws
- Through U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts

For More Information

U.S. attorneys' offices in blue pages of phone book under U.S. Government

www.usdoj.gov

Federal Trade Commission

Oversees

- All foods

Food Safety Role

- Enforces a variety of laws that protect consumers from unfair, deceptive or fraudulent practices, including deceptive and unsubstantiated advertising.

For More Information

FTC (Federal Trade Commission)
Consumer Response Center, CRC-240
Washington, DC 20580

Media inquiries: 202-326-2180
TDD: 202-326-2502

Consumers: 202-FTC-HELP
(202-382-4357)

www.ftc.gov

State and Local Governments

Oversees

- All foods within their jurisdictions

Food Safety Role

- Work with FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within state borders
- Inspect restaurants, grocery stores, and other retail food establishments, as well as dairy farms and milk processing plants, grain mills, and food manufacturing plants within local jurisdictions
- Embargo (stop the sale of) unsafe food products made or distributed within state borders

For More Information

City, county and state health, agriculture and environmental protection agencies, listed in the blue pages of the phone book under city, county and state government



1999 Edition of FDA Food Code

The Food and Drug Administration has issued a revised version of its Food Code, a reference that guides retail outlets, such as restaurants and grocery stores, and institutions, such as nursing homes, on how to prepare food to prevent food-borne illness. The new edition includes updated recommendations based on the latest findings in food safety science. The new recommendations cover such critical areas as raw eggs, juices, raw sprouts, ready-to-eat foods, hamburgers, pork, and poultry.

Provisions of the 1999 Food Code are compatible with the Hazard Analysis and Critical Control Point (HACCP) concept and terminology. HACCP is a system for ensuring food safety that involves identifying and monitoring the critical points in food preparation where the risks of food-borne hazards (microbial, chemical and physical) are greatest.

The Food Code is intended to be used by the more than 3,000 local, state and federal regulators as a model to help develop or update their own food safety rules and to be consistent with national food regulatory policy. Also, many of the more than one million retail food and food service establishments apply Food Code provisions to their own operations. Although the Food Code is neither federal law nor federal regulation and does not preempt state or local laws, authority to provide such guidance is granted by federal law. The Food Code is endorsed by the U.S. Department of Agriculture's Food Safety and Inspection Service, and the Department of Health and Human Services' Centers for Disease Control and Prevention.

The Food Code is updated every two years, to coincide with biennial meetings of the Conference for Food Protection. The conference consists of representatives from regulatory agencies at all

levels of government, the food industry, academia, and consumer organizations that work to improve food safety at the retail level. The 1999 edition incorporates many of the recommendations made at the conference. It includes new information on:

- Raw shell eggs, juices, and raw seed sprouts: The new code offers recommendations on enhanced food safety protection for people who are in a care facility, such as the elderly, who are highly susceptible to food-borne illness from these foods.
- Ready-to-eat animal-derived foods offered raw or undercooked: The new edition recommends how restaurants and other food establishments should advise consumers of the increased risk of food-borne illness from these products.
- Bare hand contact with ready-to-eat food: The 1999 code provides guidance on alternatives to "no bare hand" contact.
- Packaging of Meat and Poultry: The code refers to the USDA safe-handling instructions for retail packagers.
- Clostridium botulinum: The 1999 revision modifies recommendations about reduced oxygen packaging to more clearly address the potential hazard of the botulinum toxin in certain packaging processes.
- Cooking Steaks and Pork: The new code modifies time and temperature controls and updates the criteria about which types of beef can be served rare without a consumer advisory.

As with earlier editions, the 1999 Food Code also provides:

- detailed charts that give specific guidance for time, temperature and humidity for cooking meat and other foods derived from animals. For example, ground meat must be cooked to an internal temperature of 155 degrees Fahrenheit (68 degrees Celsius) for 15 seconds to be safe. For storing meat, the cold holding temperature is 41 F (5

degrees C). But if a refrigerator is not able to maintain food at 41 F or lower, then the food can be kept between 41 F and 45 F (7 degrees C). However, the refrigerator must be upgraded within five years of the regulatory authority's adoption of the *Food Code* so that it can hold food at 41 F or lower.

- recommendations to retail managers on how to ensure food service workers' health and hygienic practices (including restricting infected employees), how to prepare ready-to-eat foods without contaminating them with bare hands, how to clean and sanitize food utensils, and how to maintain equipment and facilities. To comply with the *Food Code*, retail managers must be able to demonstrate knowledge of food-borne illness prevention as it relates to their own food operation.

The *Food Code* also includes provisions for:

- setting time limits for holding cooked foods safely outside of controlled temperatures
- using food additives safely
- marking a date on potentially hazardous refrigerated, ready-to-eat foods that are prepared and held for more than 24 hours in a food establishment
- safely preparing meat from game animals and exotic animal species such as deer, reindeer and antelope, and ensuring that wild mushrooms are safe to eat
- ensuring honest presentation of foods to consumers
- advising consumers that certain foods should be eaten fully cooked in order to ensure their safety.

The *Food Code* also has provisions to ensure the safety of molluscan shellfish, such as oysters, clams and mussels.

Seven annexes help users apply the code's provisions uniformly and effectively to their jurisdictions. The annexes are:

- compliance and enforcement—shows model provisions on legal due process
- references—cites relevant scientific studies, laws, and regulations, cross referenced by model code section
- public health reasons—explains the rationale of each code provision

- establishment inspections—guides the planning, conduct and reporting of inspections
- HACCP—explains in detail HACCP's principles, terminology and applications
- food processing criteria—gives factors to be considered when preparing, evaluating and approving HACCP plans for certain food processing operations at the retail level
- sample forms and user aids.

The 1999 *Food Code* is available on the World Wide Web at <http://vm.cfsan.fda.gov/~dms/foodcode.html>.

It is also available from the National Technical Information Service in the following formats:

- Prepublication Document (PB99-115917INQ)—\$55 in United States, Canada and Mexico; \$110 elsewhere. Shipping now.
- Spiral Bound, 4-color format (PB99-115925INQ)—\$40 in United States, Canada and Mexico; \$80 elsewhere. Shipping end of April.
- Enhanced CD-ROM version (PB99-500506INQ)—\$69 in United States, Canada and Mexico; \$95 elsewhere. Includes Adobe Acrobat Reader 3.1 software required to view and search this version. Shipping end of April.
- Enhanced Diskette Version (PB99-501033INQ)—\$69 in United States, Canada and Mexico; \$95 elsewhere. Doesn't include Adobe Acrobat software required to use this version. Shipping end of April.
- Diskette with documents in WordPerfect 6.1 (PB99-501025INQ)—\$40 in United States, Canada and Mexico; \$70 elsewhere. A series of WordPerfect 6.1 files on one 3 1/2-inch 1.44 mb DOS diskette. Files must be decompressed onto a hard drive. Y2K compliant. Shipping end of April.

A \$5 handling fee is added to each total order for the United States, Canada and Mexico; \$10 for all others.

For more information, see <http://www.ntis.gov/yellowbk/Inty831.htm> on the World Wide Web, or call 1-800-553-6847 (or 703-605-6000), or write: NTIS, U.S. Department of Commerce, Springfield, VA 22161.

- Alcoholic beverages—Department of Treasury's Bureau of Alcohol, Tobacco and Firearms
- Drug abuse and controlled substances—Department of Justice's Drug Enforcement Administration
- Hazardous chemicals in the workplace—Department of Labor's Occupational Safety and Health Administration
- Warranties—Federal Trade Commission
- Dispensing and sales practices of pharmacies—

State board of pharmacy

- Medical practice—State certification board

General Information

If you have a general question about an FDA-regulated product, call 1-888 INFO-FDA (1-888-463-6332). But please don't report problem products or adverse reactions to this consumer information number. Use the other numbers described above.

FDA's Consumer Complaint Coordinators

To report adverse reactions or other problems with FDA-regulated products, contact the FDA district office consumer complaint coordinator for your geographic area:

Alabama—(615) 781-5385, ext. 123

Alaska—(425) 483-4949

Arizona—(714) 798-7701

Arkansas—(214) 655-5310, ext. 521

California (Northern)—(510) 337-6741

California (Southern)—(714) 798-7701

Colorado—(303) 236-3044

Connecticut—(781) 279-1675, ext. 188

Delaware—(215) 597-9064

District of Columbia—(410) 962-3593

Florida (Northern)—(407) 475-4717

Florida (Southern)—(305) 526-2800, ext. 916

Georgia—(404) 347-4001, ext. 5272

Hawaii—(510) 337-6741

Idaho—(425) 483-4949

Illinois—(312) 353-7840

Indiana—(313) 226-6260, ext. 171

Iowa—(913) 752-2440

Kansas—(913) 752-2440

Kentucky—1-800-437-2382

Louisiana—(504) 589-7186, ext. 150

Maine—(781) 279-1675, ext. 188

Maryland—(410) 962-3593

Massachusetts—(781) 279-1675, ext. 188

Michigan—(313) 226-6260, ext. 171

Minnesota—(612) 334-4100, ext. 184

Mississippi—(504) 589-7186, ext. 150

Missouri—(913) 752-2440

Montana—(425) 483-4949

Nebraska—(913) 752-2440

Nevada—(510) 337-6741

New Hampshire—(781) 279-1675, ext. 188

New Jersey—(973) 331-2917

New Mexico—(303) 236-3044

New York (Northern)—(716) 551-4461, ext. 3171

New York (Southern)—(718) 340-7000, ext. 5725

North Carolina—(404) 347-4001, ext. 5272

North Dakota—(612) 334-4100, ext. 184

Ohio—1-800-437-2382

Oklahoma—(214) 655-5310, ext. 521

Oregon—(425) 483-4949

Pennsylvania—(215) 597-9064

Rhode Island—(781) 279-1675, ext. 188

South Carolina—(404) 347-4001, ext. 5272

South Dakota—(612) 334-4100, ext. 184

Tennessee—(615) 781-5385, ext. 123

Texas—(214) 655-5310, ext. 521

Utah—(303) 236-3044

Vermont—(781) 279-1675, ext. 188

Virginia—(410) 962-3593

Washington—(425) 483-4949

West Virginia—(410) 962-3593

Wisconsin—(612) 334-4100, ext. 184

Wyoming—(303) 236-3044

Puerto Rico, U.S. Virgin Islands—(787) 729-6728

**U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
May 1997**

Overview of Dietary Supplements

What is a Dietary Supplement?

A dietary supplement is any product taken by mouth that contains a so-called "dietary ingredient" and its label clearly states that it is a dietary supplement.

The "dietary ingredients" in dietary supplements may include vitamins, minerals, herbs, and amino acids as well as substances such as enzymes, organ tissues, metabolites, extracts or concentrates. Dietary supplements can be found in many forms such as pills, tablets, capsules, liquids or powders. They must be identified on the label as a dietary supplement.

How are Dietary Supplements regulated?

The label of a dietary supplement must contain enough information about the composition of the product so that consumers can make informed choices. (The information must be presented in FDA-specified format.) The manufacturer must make sure the label information is truthful and not misleading. The manufacturer is also responsible for making sure that all the dietary ingredients in the supplements are safe. Manufacturers and distributors do not need to register with FDA or get FDA approval before producing or selling dietary supplements.

How do I report a problem or illness caused by a Dietary Supplement?

FDA can be contacted to report general complaints or concerns about food products, including dietary supplements. You may telephone or write to FDA.

If you think you have suffered a serious harmful effect or illness from a dietary supplement, your health care provider can report this by calling FDA's MedWatch hotline at 1-800-FDA-1088 or using the website <http://www.fda.gov/medwatch/report/hcp.htm>. The MedWatch program allows health care providers to report problems possibly caused by FDA-regulated products such as drugs, medical devices, medical foods and dietary supplements. The identity of the patient is kept confidential.

Consumers may also report an adverse event or illness they believe to be related to the use of a dietary supplement by calling FDA at 1-800-FDA-1088 or using the website <http://www.fda.gov/medwatch/report/consumer/consumer.htm>. FDA would like to know when a product causes a problem even if you are unsure the product caused the problem or even if you do not visit a doctor or clinic.

Are advertisements for Dietary Supplements regulated by FDA?

No. The Federal Trade Commission (FTC) handles advertising for dietary supplements and most other products sold to consumers. FDA works closely with FTC in this area, but their work is directed by different laws.

Does FDA routinely analyze the content of Dietary Supplements?

FDA has limited resources to analyze the composition of food products, including dietary supplements. So, FDA focuses first on public health emergencies and products that may have caused injury or illness. Then products thought to be fraudulent or in violation of the law are analyzed. FDA uses the remaining funds for routine monitoring of products pulled from store shelves. FDA does not analyze supplement products before they are sold to consumers. The manufacturer is responsible for ensuring that the ingredient list is accurate and that the ingredients are safe. They are also required to make sure that the content matches the amount declared on the label.

FDA does not have adequate resources to analyze dietary products sent by consumers who want to know their content. Instead, consumers may contact the manufacturer or a commercial laboratory.

Are all ingredients required to be declared on the label?

Other ingredients in the product must be listed in the ingredient statement beneath the "Supplement Facts" panel. The types of ingredients listed there would include gelatin, sugars, starch, colors, stabilizers and preservatives.

Are there restrictions on size of the pill or how much of a nutrient can be in one serving of a Dietary Supplement?

There are no rules that limit a serving size or the amount of nutrients in any form of dietary supplements. This decision is made by the manufacturer and does not require FDA review or approval. For one dietary ingredient, ephedrine alkaloids, FDA has proposed to permit serving sizes of 8 mg or less.

What kinds of claims can be made on the labels of Dietary Supplements?

As with other food products, the manufacturer can put certain claims on the product label. These claims tell consumers about the nutritional value of the product. Claims defined by FDA to describe the nutrient content of a product, like "good source" or "high", can appear on the label if one serving meets the definition. There are specific rules as to which substances can be listed using these nutrient content claims.

Manufacturers can also put FDA-approved "health claims" on a product label. Health claims describe the connection between a nutrient or food substance and a disease or health-related condition. Claims about these diet/disease relationships can appear on the label if the content of the product meets the FDA requirements and if the claim is one of the approved health claims.

Why do some supplements have wording that says: "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or

prevent any disease"?

Certain statements may be included on the label that give the manufacturer's description of the role of the dietary supplement. These statements are not authorized by FDA. The manufacturer is responsible for ensuring that these statements are accurate and truthful. For this reason, the law says that if a dietary supplement label includes this information, it must also state that FDA has not evaluated the statement.

Where can I get information about a specific Dietary Supplement?

Manufacturers do not need FDA approval to sell their supplement products. This means that FDA does not keep a list of manufacturers or products on the market. If you want more specific information than the label tells you about the products, you may contact the manufacturer directly.

Office of Special Nutritionals, May 1997

Hypertext updated by ear/dms 1999-APR-13

U. S. Food and Drug Administration
FDA Consumer
September - October 1998; Revised January 1999

An FDA Guide to Dietary Supplements

by Paula Kurtzweil

Set between a Chinese restaurant and a pizza and sub sandwich eatery, a Rockville health food store offers yet another brand of edible items: Bottled herbs like cat's claw, dandelion root, and blessed thistle. Vitamins and minerals in varying doses. Herbal and nutrient concoctions whose labels carry claims about relieving pain, "energizing" and "detoxifying" the body, or providing "guaranteed results."

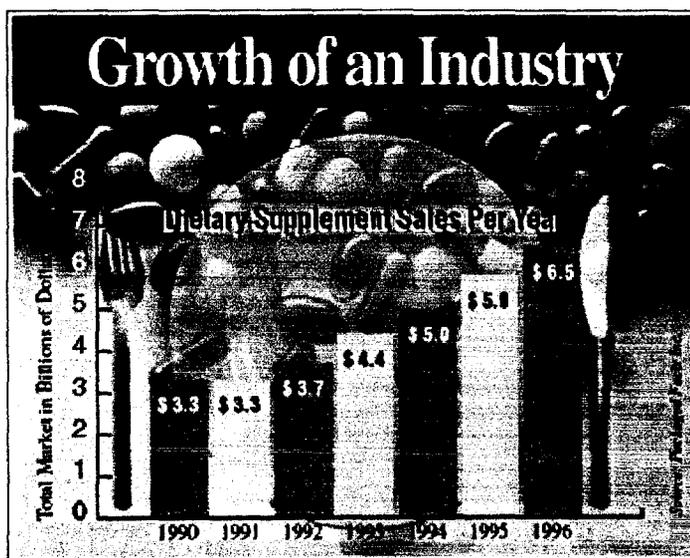
This store sells dietary supplements, some of the hottest selling items on the market today. Surveys show that more than half of the U.S. adult population uses these products. In 1996 alone, consumers spent more than \$6.5 billion on dietary supplements, according to Packaged Facts Inc., a market research firm in New York City.

But even with all the business they generate, consumers still ask questions about dietary supplements: Can their claims be trusted? Are they safe? Does the Food and Drug Administration approve them?

Many of these questions come in the wake of the 1994 Dietary Supplement Health and Education Act, or DSHEA, which set up a new framework for FDA regulation of dietary supplements. It also created an office in the National Institutes of Health to coordinate research on dietary supplements, and it called on President Clinton to set up an independent dietary supplement commission to report on the use of claims in dietary supplement labeling.

In passing DSHEA, Congress recognized first, that many people believe dietary supplements offer health benefits and second, that consumers want a greater opportunity to determine whether supplements may help them. The law essentially gives dietary supplement manufacturers freedom to market more products as dietary supplements and provide information about their products' benefits--for example, in product labeling.

The Council for Responsible Nutrition, an organization of manufacturers of dietary supplements and their suppliers, welcomes the change. "Our philosophy has been ... to maintain consumer access to products and access to information [so that consumers can] make informed choices," says John Cordaro, the group's president and chief executive officer.



But in choosing whether to use dietary supplements, FDA answers consumers' questions by noting that under DSHEA, FDA's requirement for premarket review of dietary supplements is less than that over other products it regulates, such as drugs and many additives used in conventional foods.

This means that consumers and manufacturers have responsibility for checking the safety of dietary supplements and determining the truthfulness of label claims.

Anatomy of the New Requirements for Dietary Supplement Labels

Information that will be required on the labels of dietary supplements includes:

- Statement of identity (e.g., "ginseng")
- Net quantity of contents (e.g., "60 capsules")
- Structure-function claim and the statement "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- Directions for use (e.g., "Take one capsule daily.")
- Supplement Facts panel (lists serving size, amount, and active ingredient)
- Other ingredients in descending order of predominance and by common name or proprietary blend.
- Name and place of business of manufacturer, packer or distributor. This is the address to write for more product information.

View the [dietary supplement labels in PDF format \(252K\)](#).

What Is a Dietary Supplement?

Traditionally, dietary supplements referred to products made of one or more of the essential nutrients, such as vitamins, minerals, and protein. But DSHEA broadens the definition to include, with some exceptions, any product intended for ingestion as a supplement to the diet. This includes vitamins; minerals; herbs, botanicals, and other plant-derived substances; and amino acids (the individual building blocks of protein) and concentrates, metabolites, constituents and extracts of these substances.

It's easy to spot a supplement because DSHEA requires manufacturers to include the words "dietary supplement" on product labels. Also, starting in March 1999, a "Supplement Facts" panel will be required on the labels of most dietary supplements.

Dietary supplements come in many forms, including tablets, capsules, powders, softgels, gelcaps, and liquids. Though commonly associated with health food stores, dietary supplements also are sold in grocery, drug and national discount chain stores, as well as through mail-order catalogs, TV programs, the Internet, and direct sales.

FDA oversees safety, manufacturing and product information, such as claims, in a product's labeling, package inserts, and accompanying literature. The Federal Trade Commission regulates the advertising of dietary supplements.

One thing dietary supplements are not is drugs. A drug, which sometimes can be derived from plants used as traditional medicines, is an article that, among other things, is intended to diagnose, cure, mitigate, treat, or prevent diseases. Before marketing, drugs must undergo clinical studies to determine their effectiveness, safety, possible interactions with other substances, and appropriate

dosages, and FDA must review these data and authorize the drugs' use before they are marketed. FDA does not authorize or test dietary supplements.

A product sold as a dietary supplement and touted in its labeling as a new treatment or cure for a specific disease or condition would be considered an unauthorized--and thus illegal--drug. Labeling changes consistent with the provisions in DSHEA would be required to maintain the product's status as a dietary supplement.

Another thing dietary supplements are not are replacements for conventional diets, nutritionists say. Supplements do not provide all the known--and perhaps unknown--nutritional benefits of conventional food.

Monitoring for Safety

As with food, federal law requires manufacturers of dietary supplements to ensure that the products they put on the market are safe. But supplement manufacturers do not have to provide information to FDA to get a product on the market, unlike the food additive process often required of new food ingredients. FDA review and approval of supplement ingredients and products is not required before marketing.

Food additives not generally recognized as safe must undergo FDA's premarket approval process for new food ingredients. This requires manufacturers to conduct safety studies and submit the results to FDA for review before the ingredient can be used in marketed products. Based on its review, FDA either authorizes or rejects the food additive.

In contrast, dietary supplement manufacturers that wish to market a new ingredient (that is, an ingredient not marketed in the United States before 1994) have two options. The first involves submitting to FDA, at least 75 days before the product is expected to go on the market, information that supports their conclusion that a new ingredient can reasonably be expected to be safe. Safe means that the new ingredient does not present a significant or unreasonable risk of illness or injury under conditions of use recommended in the product's labeling.

The information the manufacturer submits becomes publicly available 90 days after FDA receives it.

Another option for manufacturers is to petition FDA, asking the agency to establish the conditions under which the new dietary ingredient would reasonably be expected to be safe. To date, FDA's Center for Food Safety and Applied Nutrition has received no such petitions.

Under DSHEA, once a dietary supplement is marketed, FDA has the responsibility for showing that a dietary supplement is unsafe before it can take action to restrict the product's use. This was the case when, in June 1997, FDA proposed, among other things, to limit the amount of ephedrine alkaloids in dietary supplements (marketed as ephedra, Ma huang, Chinese ephedra, and epitonin, for example) and provide warnings to consumers about hazards associated with use of dietary supplements containing the ingredients. The hazards ranged from nervousness, dizziness, and changes in blood pressure and heart rate to chest pain, heart attack, hepatitis, stroke, seizures, psychosis, and death. The proposal stemmed from FDA's review of adverse event reports it had received, scientific literature, and public comments. FDA has received many comments on the 1997 proposal and was reviewing them at press time.

Also in 1997, FDA identified contamination of the herbal ingredient plantain with the harmful herb *Digitalis lanata* after receiving a report of a complete heart block in a young woman. FDA traced all

use of the contaminated ingredient and asked manufacturers and retailers to withdraw these products from the market. (For information about other potentially dangerous dietary supplements, see "Supplements Associated with Illnesses and Injuries.")

DSHEA also gives FDA authority to establish good manufacturing practices, or GMPs, for dietary supplements. In a February 1997 advance notice of proposed rulemaking, the agency said it would establish dietary supplement GMPs if, after public comment, it determined that GMPs for conventional food are not adequate to cover dietary supplements, as well. GMPs, the agency said, would ensure that dietary supplements are made under conditions that would result in safe and properly labeled products. At press time, FDA was reviewing comments on the 1997 notice.

Some supplement makers may already voluntarily follow GMPs devised, for example, by trade groups.

Besides FDA, individual states can take steps to restrict or stop the sale of potentially harmful dietary supplements within their jurisdictions. For example, Florida has banned some ephedra-containing products, and other states have said they are considering similar action.

Also, the industry strives to regulate itself, the Council for Responsible Nutrition's Cordaro says. He cites the GMPs that his trade group and others developed for their member companies. FDA is reviewing these GMPs as it considers whether to pursue mandatory industry-wide GMPs. Another example of self-regulation, Cordaro says, is the voluntary use of a warning about ephedra products that his organization drafted. He says that about 90 percent of U.S. manufacturers of products containing ephedra alkaloids now use this warning label.

Understanding Claims

Claims that tout a supplement's healthful benefits have always been a controversial feature of dietary supplements. Manufacturers often rely on them to sell their products. But consumers often wonder whether they can trust them.

Under DSHEA and previous food labeling laws, supplement manufacturers are allowed to use, when appropriate, three types of claims: nutrient-content claims, disease claims, and nutrition support claims, which include "structure-function claims."

Nutrient-content claims describe the level of a nutrient in a food or dietary supplement. For example, a supplement containing at least 200 milligrams of calcium per serving could carry the claim "high in calcium." A supplement with at least 12 mg per serving of vitamin C could state on its label, "Excellent source of vitamin C."

Disease claims show a link between a food or substance and a disease or health-related condition. FDA authorizes these claims based on a review of the scientific evidence. Or, after the agency is notified, the claims may be based on an authoritative statement from certain scientific bodies, such as the National Academy of Sciences, that shows or describes a well-established diet-to-health link. As of this writing, certain dietary supplements may be eligible to carry disease claims, such as claims that show a link between:

- the vitamin folic acid and a decreased risk of neural tube defect-affected pregnancy, if the supplement contains sufficient amounts of folic acid
- calcium and a lower risk of osteoporosis, if the supplement contains sufficient amounts of calcium
- psyllium seed husk (as part of a diet low in cholesterol and saturated fat) and coronary heart

disease, if the supplement contains sufficient amounts of psyllium seed husk.

Nutrition support claims can describe a link between a nutrient and the deficiency disease that can result if the nutrient is lacking in the diet. For example, the label of a vitamin C supplement could state that vitamin C prevents scurvy. When these types of claims are used, the label must mention the prevalence of the nutrient-deficiency disease in the United States.

These claims also can refer to the supplement's effect on the body's structure or function, including its overall effect on a person's well-being. These are known as structure-function claims.

Examples of structure-function claims are:

- Calcium builds strong bones.
- Antioxidants maintain cell integrity.
- Fiber maintains bowel regularity.

Manufacturers can use structure-function claims without FDA authorization. They base their claims on their review and interpretation of the scientific literature. Like all label claims, structure-function claims must be true and not misleading.

Structure-function claims can be easy to spot because, on the label, they must be accompanied with the disclaimer "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

Manufacturers who plan to use a structure-function claim on a particular product must inform FDA of the use of the claim no later than 30 days after the product is first marketed. While the manufacturer must be able to substantiate its claim, it does not have to share the substantiation with FDA or make it publicly available.

If the submitted claims promote the products as drugs instead of supplements, FDA can advise the manufacturer to change or delete the claim.

Because there often is a fine line between disease claims and structure-function claims, FDA in April 1998 proposed regulations that would establish criteria under which a label claim would or would not qualify as a disease claim. Among label factors FDA proposed for consideration are:

- the naming of a specific disease or class of diseases
- the use of scientific or lay terminology to describe the product's effect on one or more signs or symptoms recognized by health-care professionals and consumers as characteristic of a specific disease or a number of different specific diseases
- product name
- statements about product formulation
- citations or references that refer to disease
- use of the words "disease" or "diseased"
- art, such as symbols and pictures
- statements that the product can substitute for an approved therapy (for example, a drug).

FDA's proposal is consistent with the guidance on the distinction between structure-function and disease claims provided in the 1997 report by the President's Commission on Dietary Supplement Labels.

If shoppers find dietary supplements whose labels state or imply that the product can help diagnose, treat, cure, or prevent a disease (for example, "cures cancer" or "treats arthritis"), they should realize that the product is being marketed illegally as a drug and as such has not been evaluated for safety or effectiveness.

FTC regulates claims made in the advertising of dietary supplements, and in recent years, that agency has taken a number of enforcement actions against companies whose advertisements contained false and misleading information. The actions targeted, for example, erroneous claims that chromium picolinate was a treatment for weight loss and high blood cholesterol. An action in 1997 targeted ads for an ephedrine alkaloid supplement because they understated the degree of the product's risk and featured a man falsely described as a doctor.

Fraudulent Products

Consumers need to be on the lookout for fraudulent products. These are products that don't do what they say they can or don't contain what they say they contain. At the very least, they waste consumers' money, and they may cause physical harm.

Fraudulent products often can be identified by the types of claims made in their labeling, advertising and promotional literature. Some possible indicators of fraud, says Stephen Barrett, M.D., a board member of the National Council Against Health Fraud, are:

- Claims that the product is a secret cure and use of such terms as "breakthrough," "magical," "miracle cure," and "new discovery." If the product were a cure for a serious disease, it would be widely reported in the media and used by health-care professionals, he says.
- "Pseudomedical" jargon, such as "detoxify," "purify" and "energize" to describe a product's effects. These claims are vague and hard to measure, Barrett says. So, they make it easier for success to be claimed "even though nothing has actually been accomplished," he says.
- Claims that the product can cure a wide range of unrelated diseases. No product can do that, he says.
- Claims that a product is backed by scientific studies, but with no list of references or references that are inadequate. For instance, if a list of references is provided, the citations cannot be traced, or if they are traceable, the studies are out-of-date, irrelevant, or poorly designed.
- Claims that the supplement has only benefits--and no side effects. A product "potent enough to help people will be potent enough to cause side effects," Barrett says.
- Accusations that the medical profession, drug companies and the government are suppressing information about a particular treatment. It would be illogical, Barrett says, for large numbers of people to withhold information about potential medical therapies when they or their families and friends might one day benefit from them.

Though often more difficult to do, consumers also can protect themselves from economic fraud, a practice in which the manufacturer substitutes part or all of a product with an inferior, cheaper ingredient and then passes off the fake product as the real thing but at a lower cost. Varro Tyler, Ph.D., Sc.D., a distinguished professor emeritus of pharmacognosy (the study of medicinal products in their crude, or unprepared, form) at Purdue University in West LaFayette, Ind., advises consumers to avoid products sold for considerably less money than competing brands. "If it's too cheap, the product is probably not what it's supposed to be," he says.

Quality Products

Poor manufacturing practices are not unique to dietary supplements, but the growing market for supplements in a less restrictive regulatory environment creates the potential for supplements to be prone to quality-control problems. For example, FDA has identified several problems where some manufacturers were buying herbs, plants and other ingredients without first adequately testing them to determine whether the product they ordered was actually what they received or whether the ingredients were free from contaminants.

To help protect themselves, consumers should:

- Look for ingredients in products with the U.S.P. notation, which indicates the manufacturer followed standards established by the U.S. Pharmacopoeia.
- Realize that the label term "natural" doesn't guarantee that a product is safe. "Think of poisonous mushrooms," says Elizabeth Yetley, Ph.D., director of FDA's Office of Special Nutritionals. "They're natural."
- Consider the name of the manufacturer or distributor. Supplements made by a nationally known food and drug manufacturer, for example, have likely been made under tight controls because these companies already have in place manufacturing standards for their other products.
- Write to the supplement manufacturer for more information. Ask the company about the conditions under which its products were made.

Reading and Reporting

Consumers who use dietary supplements should always read product labels, follow directions, and heed all warnings.

Supplement users who suffer a serious harmful effect or illness that they think is related to supplement use should call a doctor or other health-care provider. He or she in turn can report it to FDA MedWatch by calling 1-800-FDA-1088 or going to www.fda.gov/medwatch/report/hcp.htm on the MedWatch Website. Patients' names are kept confidential.

Consumers also may call the toll-free MedWatch number or go to www.fda.gov/medwatch/report/consumer/consumer.htm on the MedWatch Website to report an adverse reaction. To file a report, consumers will be asked to provide:

- name, address and telephone number of the person who became ill
- name and address of the doctor or hospital providing medical treatment
- description of the problem
- name of the product and store where it was bought.

Consumers also should report the problem to the manufacturer or distributor listed on the product's label and to the store where the product was bought.

Today's Dietary Supplements

The report of the President's Commission on Dietary Supplement Labels, released in November 1997, provides a look at the future of dietary supplements. It encourages researchers to find out whether consumers want and can use the information allowed in dietary supplement labeling under DSHEA. It encourages studies to identify more clearly the relationships between dietary supplements and health maintenance and disease prevention. It urges FDA to take enforcement action when questions about a product's safety arise. And it suggests that FDA and the industry work together to develop guidelines

on the use of warning statements on dietary supplement labels.

FDA generally concurred with the commission's recommendations in the agency's 1998 proposed rule on dietary supplement claims.

While much remains unknown about many dietary supplements--their health benefits and potential risks, for example--there's one thing consumers can count on: the availability of a wide range of such products. But consumers who decide to take advantage of the expanding market should do so with care, making sure they have the necessary information and consulting with their doctors and other health professionals as needed.

"The majority of supplement manufacturers are responsible and careful," FDA's Yetley says. "But, as with all products on the market, consumers need to be discriminating. FDA and industry have important roles to play, but consumers must take responsibility, too."

Paula Kurtzweil is a member of FDA's public affairs staff.

Supplement Your Knowledge

Some sources for additional information on dietary supplements are:

Federal Agencies

Food and Drug Administration:

Office of Consumer Affairs
HFE-88
Rockville, MD 20857

Food Information Line
1-800-FDA-4010
(202) 205-4314 in the Washington, D.C., area

FDA Website: www.cfsan.fda.gov/~dms/supplmnt.html

Federal Trade Commission
Public Reference Branch
Room 130
Washington, DC 20580
www.ftc.gov

National Institute on Aging
NIA Information Center
P.O. Box 8057
Gaithersburg, MD 20898-8057
1-800-222-2225
TTY: 1-800-222-4225
<http://128.231.160.11/nia/health/pubpub/hormrev.htm>

Health Professional Organizations

American Dietetic Association
216 W. Jackson Blvd.
Chicago, IL 60606-6995
1-800-366-1655 (recorded messages)
1-900-225-5267 (to talk to a registered dietitian)
www.eatright.org

Expert Advice

Before starting a dietary supplement, it's always wise to check with a medical doctor. It is especially important for people who are:

- pregnant or breastfeeding
- chronically ill
- elderly
- under 18
- taking prescription or over-the-counter medicines. Certain supplements can boost blood levels of certain drugs to dangerous levels.

Varro Tyler, Ph.D., Sc.D., distinguished professor emeritus of pharmacognosy at Purdue University, cites as examples garlic and the supplement ginkgo biloba. Both can thin the blood, which can be hazardous, he says, for people taking prescription medicines that also thin the blood.

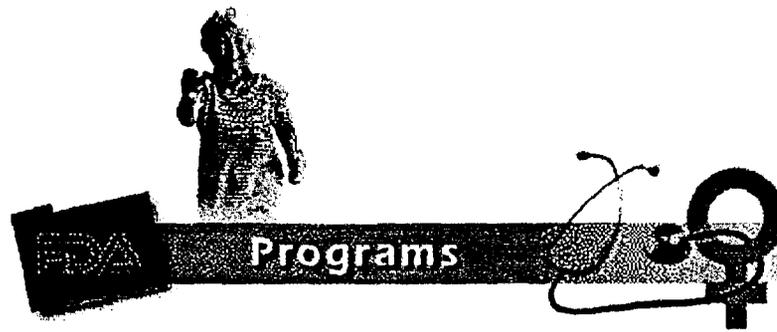
In addition to medical doctors, other health-care professionals, such as registered pharmacists, registered dietitians and nutritionists, also can be sources of information about dietary supplements.

--P.K.

Publication No. (FDA) 99-2323

This is a mirror of the page at http://www.fda.gov/fdac/features/1998/598_guid.html

[Home](#)



FDA Office of Women's Health U.S. Food and Drug Administration

The Office of Women's Health (OWH) was created by the Food and Drug Administration (FDA) in 1994. Its establishment began a new chapter in the agency's commitment to women's health issues. The FDA has jurisdiction over the drugs, medical devices, vaccines, blood and tissue products, foods and cosmetics on which every American woman and her family depend -- about 25% of every consumer dollar. Thus, OWH has an almost unlimited number of women's health issues in which to engage. In three years, OWH has established itself as an effective voice for women's health concerns. Here are some major activities and accomplishments.

SPONSORING-GROUNDBREAKING RESEARCH AND OTHER PRIORITY PROJECTS CONDUCTED BY FDA STAFFERS

OWH funds research and education/outreach programs on pressing women's health issues. It utilizes a competitive peer review process for selection of the highest quality projects, with an emphasis on projects with the greatest potential for significantly contributing to knowledge of women's health in a brief time frame. OWH has awarded \$6 million in grants for these projects to date.

Through this mechanism OWH has funded more than 50 scientific projects, including research in the following areas: breast and ovarian cancer, women and HIV, women and cardiovascular disease, osteoporosis, breast implant safety, the effects of estrogen, and women and autoimmune disease.

Public education funded by OWH has included a series of minority empowerment workshops on women's health in the Mid-Atlantic region, the production of a breast cancer awareness play and panel discussion in African-American churches in Texas and at Howard University in the District of Columbia, a Hispanic women's health conference for health professionals in south Florida, and the translation of brochures on mammography and pap smears into several Asian languages and dialects.

PUBLIC AWARENESS PARTNERING WITH GRASS ROOTS WOMEN'S GROUPS

OWH has initiated a major public awareness program, "Women's Health: Take Time To Care," to bring important health promotion messages to mid-life and older women, with an emphasis on the under served. The message is "Use Medicines Wisely," in order to raise awareness about better health practices among the target group and their families, and to reduce the annual cost of \$75 billion in

doctors' visits, hospitalizations, and lost wages resulting from improper use of medicines.

In the Spring of 1997, a full week of activities was held in pilot programs in both Hartford, CN and Chicago, IL. In each city, numerous events coordinated by OWH were held by non-profit groups, social service agencies, government and other entities to distribute attractive, accessible materials and create a dialogue around the importance of taking medication safely and properly. By partnering with drug and grocery stores, the campaign distributed over 235,000 pieces of literature and engaged thousands of women.

In 1998, OWH will roll out the program nationally, with "Take Time To Care" weeks in at least fifteen metropolitan areas. Partnerships with other government entities will take the program to rural areas, historically black colleges, and Indian reservations. Involvement of many of the nation's large drug chains will result in reaching millions of women.

LEADERSHIP ON WOMEN IN CLINICAL TRIALS/GENDER EFFECTS

One of the core missions of OWH is to encourage industry to include women in their studies and to encourage the participation of women in clinical trials of FDA-regulated products. The office advances this agenda, and that of encouraging the analysis of clinical trial data for gender differences, by:

- Sponsoring major scientific conferences, proposing new regulations and frequently speaking on the topic;
- with the Center for Drugs, co-chairing the agency-wide Gender Effects Steering Committee which addresses scientific and policy issues related to gender-specific responses to products; and
- sponsoring agency initiatives for collecting and analyzing gender-specific data, including a pilot tracking system to monitor the enrollment of women in clinical trials.

ACTING AS AN ADVOCATE FOR WOMEN'S HEALTH IN AGENCY ACTIONS

OWH works to raise awareness and provide focus throughout the FDA, the Public Health Service and the Clinton Administration, on important women's health issues over which FDA has jurisdiction. OWH has provided scientific and policy input on many of today's leading women's health issues. These include questions involving the safe and effective use of silicone breast implants, thalidomide, hormone replacement therapy, contraceptive products, ingredients in cosmetics, bone measurement devices, at home devices to fight premature labor, mammography, use of folic acid prior to pregnancy, and much more.

WORKING WITH EXTERNAL CONSTITUENCIES

The OWH staff provides information on women's health issues to Congress, the press, health professionals, women's health advocates, and the lay public in a multitude of ways, among them:

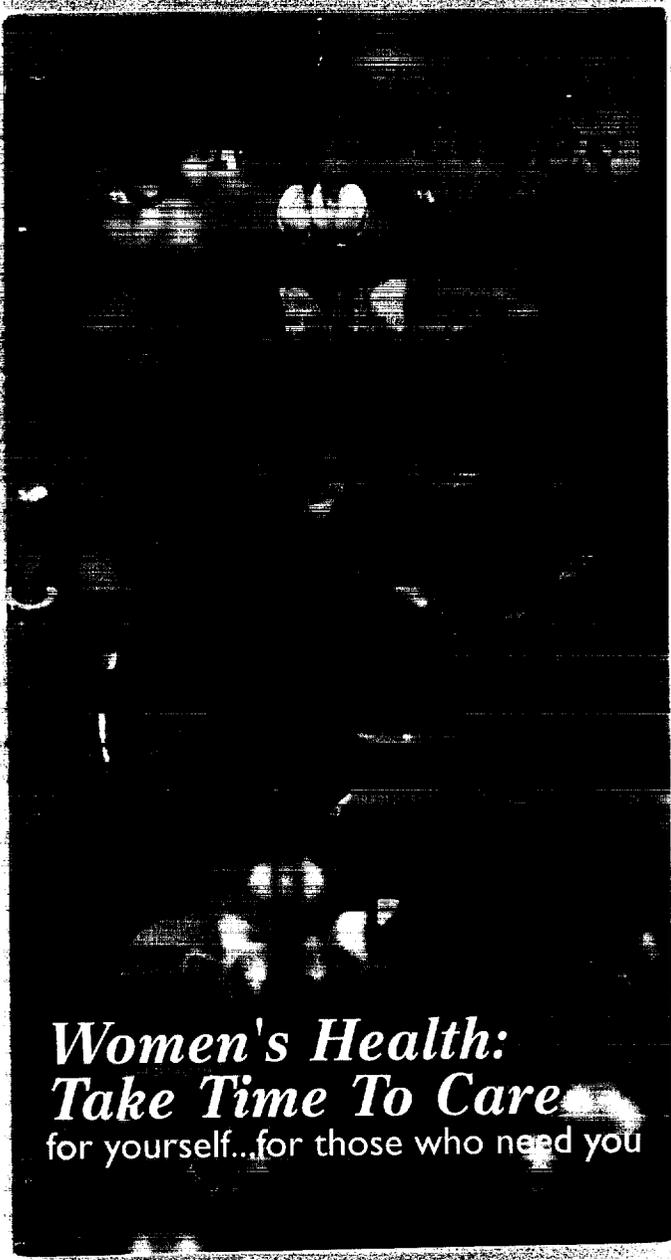
- Publishing articles for scientific journals;
- producing educational publications for consumers;
- delivering speeches to the full-range of audiences and constituencies interested in women's

- health; and
- maintaining our website of useful women's health information.

[Mission](#) | [Programs](#) | [Information](#) | [Links](#) | [Feedback](#) | [What's New](#)

(Hypertext updated by clb 1999-FEB-10)





Women's Health:
Take Time To Care
for yourself...for those who need you

USE MEDICINES WISELY

About 30% to 50% of those who use medicines do not use them as directed. This causes more doctor visits, hospital stays, lost wages and changed prescriptions. All this costs Americans as much as \$76.6 billion each year.

Women often take care of medicines for the whole family, as well as themselves. So we need to read the label, avoid problems, ask questions and keep a record.

READ THE LABEL

Before you take any medicine read the label. The label should show:

List of ingredients - If you know you are allergic to anything in the medicine, don't use it. Ask your doctor or pharmacist for a different medicine.

Warnings - Read these carefully.

The expiration date - Do not use a medicine after the date on the bottle. It may not work as well.

For more information on your medicines ask your pharmacist.

AVOID PROBLEMS

Medicines can cause problems, or side effects; such as sleepiness, vomiting, bleeding, headaches or rashes. Ask about the side effects of the medicines you are taking. Talk with your doctor, pharmacist, or nurse.

Organize your medicines.

Do not skip taking your medicines.

Do not share medicines.

Do not take medicine in the dark.

ASK QUESTIONS

- What is the medicine's name?
- Is there a generic available?
- Why am I taking this medicine?
- When should I take it?
- Should I take this on an empty stomach or with food?
- Is it safe to drink alcohol with it?
- If I forget to take it, what should I do?
- How much should I take?
- How long am I to take it?
- What problems should I watch for?

Talk with your doctor, pharmacist or nurse. She/he will be happy to help you.

List any allergies _____

Doctor _____

Phone number _____

Drug store _____

Phone number _____

KEEP A RECORD OF MEDICINES YOU USE

Check boxes for the ones you use:

- Aspirin or other pain/headache/fever medicine
- Allergy medicine
- Antacids
- Cold medicine
- Cough medicine
- Diet pills
- Laxatives
- Sleeping pills
- Vitamins
- Minerals
- Herbals
- Others _____

NAME: _____

LIST YOUR PRESCRIPTION MEDICINES

Name of My Medicine	How Much Do I Take	When Do I Take It	What Do I Use It For
XXXX EXAMPLE	1 tablet 400 mg	3 times a day after meals	Arthritis

KEEP THIS IN YOUR PURSE AND SHOW IT TO YOUR DOCTORS,
PHARMACIST OR NURSE.

WORDS YOU SHOULD KNOW

Generic Medicine - A drug that has the same medicine as the brand name drug. This will work the same way as the brand name drug, but often costs less.

Prescription medicine - A drug that can only be bought with permission from the doctor.

Pharmacist - The person in the drug store who is trained to fill your prescription and answer questions.

Women's Health: Take Time To Care for yourself...for those who need you



FDA
Office of
Women's
Health

U.S. Food and Drug Administration

Women's Health: Take Time To Care

[Program Summary](#)[Consumer Materials](#)[Supporters](#)

The Food and Drug Administration (FDA) regulates medicines to assure that they are safe and effective, when taken as directed. Yet, thirty to fifty percent of people do not take these medications as prescribed. A recent study estimated that the inappropriate use of medicine costs the American public \$76.6 billion a year.

The FDA's Office of Women's Health (OWH) has developed Women's Health: Take Time to Care (TTTC), a grassroots public awareness campaign to reach millions of women to "Use Medicines Wisely." Drug stores, public service organizations, health and senior facilities, as well as the media partnered with us in this campaign. We all recognized that women, as the principal users and dispensers of medications, need to be more aware of the consequences of their choices/actions for themselves and their families.

In 1997-98 the FDA/OWH and field staff acted as the catalyst to galvanize 20 pilot cities and selected rural areas. The program is a new model for federal government forming beneficial partnerships which stimulate community action by elected officials, grassroots organizations, businesses, hospitals, professional associations and others.

In 1999, due to popular demand, FDA and the National Association of Chain Drug Stores will offer this program to every community across the country that wants to reach women and their families with the message to "Use Medicines Wisely."



Public Affairs Specialists

FDA's Walking Encyclopedias

by Betsy Adams and John Henkel

From dietary supplements, to food labels, to how to give medicines to kids—believe me, I've heard it all," says Mary Margaret Richardson, FDA's St. Louis-based public affairs specialist (PAS). "The broad questions on these and other subjects that were important to people 20 years ago—about their own health and safety, or the well-being of their families—are still important to them today."

FDA's PAS's spend considerable time answering questions from the general public, as well as from the news media and just about anyone else wanting to know more about the products FDA regulates. Responding to queries on a wide variety of subjects—from female condoms to electromagnetic fields, from food labeling to mammography—the agency's 44 • PAS's are walking encyclopedias.

They act as teachers, giving workshops and seminars to organizations about FDA's work, and as representatives, appearing on broadcast media and assisting reporters in news story development. They also can be found helping the consumers across the country who call the myriad FDA district offices looking for information.

Though consumers have been asking the same kinds of health and safety questions since the 1960s and 1970s, FDA's PAS's are using more and different means to get answers. When Richardson started work as a PAS (then called a consumer affairs officer, or CAO) in 1971, she spent most of her time speaking one-on-one to health

professionals, consumers, senior citizens, students, and other individuals.

"Today, I use the media—particularly TV and radio—a lot more of the time," she says. "Through the media I can reach a wider audience with FDA's messages."

Those messages have changed, too. Consumers no longer take the government's word on faith. They want all the information they can get—and then make up their own minds.

"We used to deliver the message: Because FDA is here, you're safe. Today we say: Because FDA is here, you *know* more," says Richardson, adding that no single agency can provide total safety to the public.

Lois Meyer, a PAS who recently retired after a 30-year FDA career in Buffalo, N.Y., thinks of her years with FDA as "both a teacher and a learner" experience.

"I never stopped having to learn new things about FDA programs, whether they involved medical devices or food labels," she says. "In turn, I served as a teacher, a resource both for our publics and for FDAers in our field office who needed to know what the public was saying."

FDA's PAS's have no standard training regimen or specific background as a requirement for the job. Some previously worked for the agency in another capacity, such as an investigator or compliance officer. Others are experienced in public relations. Though many perfect their trade by on-the-job experience, all bring to the job an enthusiasm



Mary Margaret Richardson (standing), public affairs specialist at FDA's St.

Louis office, explains food labeling to a group of dietitian students at St.

Louis University.

for FDA and exemplary public speaking and interpersonal skills.

In Meyer's case, a large part of her job was teaching people how to help themselves. For example, patients often called with questions about their medicines—questions that would best be answered by their own pharmacists.

"Sometimes the most helpful thing to do is make people aware of the tremendous resources already at their disposal," Meyer says. "If a consumer wants to know how much lead is in a piece of dinnerware, the people who sold you the

product have a responsibility to help you get that information."

Established in 1952 as a cadre of consumer consultants, the original team of consumer affairs officers included only women—many of them homemakers who worked part time—with a home economics background. Today they include men, and their backgrounds are many and varied.

In 1972, Juan Tijerina of FDA's San Antonio resident post became the first man to join the group. Tijerina had been an FDA chemist for 10 years.

"I like to talk to people," he says. "I like to travel, and when the job for a bilingual CAO opened up, I jumped at the chance."

Tijerina remembers his first national meeting with the other CAOs.

"I could feel hundreds of eyes on me," he says, "not just those of my 55 women co-workers, but others at headquarters—wondering, I guess, why a man would want to join the group.

"I guess my motivation was much the same as the women's. I wanted to help people and help them understand the work we do," he says.

Recently Tijerina and two other Spanish-speaking PAS's—Al Gonzalez from San Juan and Estela Niella-Brown from Miami—went on a special assignment to Mexico City to teach food manufac-

How to Contact a Public Affairs Specialist

Consumers seeking information about FDA and the products it regulates can reach a public affairs specialist in their region by looking up the phone number of the FDA district office in the nearest large city's phone directory. One warning: FDA is not listed in the "F" section of federal government agency listings. Instead, it's found in the "H's" under "Health and Human Services" as an agency of that department.

Some FDA district offices have toll-free numbers, others require a long-distance call for those outside the district's local dialing area. FDA "resident posts," found in many smaller cities and listed in the phone book, also can for-

ward questions to an appropriate PAS.

What kinds of questions can consumers ask? "Just about anything that has to do with FDA's regulatory realm is fair game," says Mary Margaret Richardson, PAS for FDA's St. Louis office. "This includes drugs, biologics, medical devices, veterinary medicine, and food safety."

Richardson says consumers sometimes call PAS's to report faulty products or adverse reactions. These calls typically are subsequently referred to an FDA complaint coordinator. Sometimes, Richardson says, she gets calls concerning non-FDA responsibilities such as household devices or meat and poultry safety. She refers these to the Consumer Product Safety Commission, the U.S.

Department of Agriculture, or other appropriate agency.

Because PAS's are sometimes in the field and unavailable to take phone questions, Richardson suggests that callers "make good use of the phone mail system" PAS's have. When in remote locations, she checks her phone mail "a couple times a day" and tries to return calls promptly. She asks, however, that callers "leave clear, detailed messages with a phone number where they can be reached. If they are seeking, say, a publication, they should give the publication name and number along with their address." ■

—J.H.

urers about requirements of the 1990 Nutrition Labeling and Education Act. Mexican products exported to the United States must bear the new food label, and education—in Spanish—is important to make sure that country's producers understand legal requirements.

Bilingual PAS's are frequently called on to use their language skills. For example, when a brand of semi-soft white cheese favored by Miami's Hispanic communities was recalled due to bacterial contamination, Niella-Brown worked with Miami's Spanish-language media to get the story out to consumers most likely to have bought the product.

As they deal daily with important health issues, PAS's inevitably are involved in experiences touched with sadness. New York City PAS Herman "Bernie" Janiger remembers a thank-you letter from a woman whose infant had died from listeria-tainted food.

"The baby was just two-and-a-half weeks old," Janiger says. "The mother was griefstricken, of course, but amazingly she took the time to write to tell me how much she appreciated my work to inform consumers about problems, that I must have saved lots of other

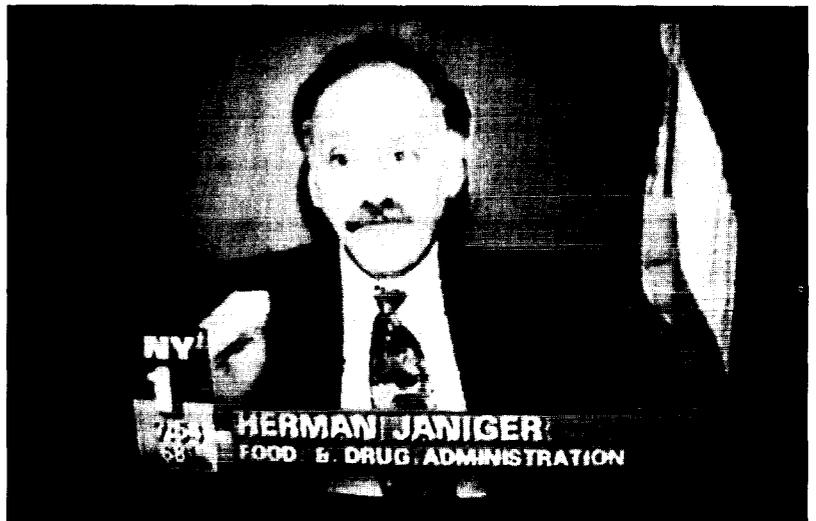
lives, even though it was too late for her baby."

Other memories are happier. Janiger helped editors of the Random House Unabridged Dictionary with precise definitions for medical terms, and is acknowledged in the dictionary as a special consultant. He was called, too, by a researcher with the daytime TV drama "One Life To Live" for information on a drug's name and potential effects. The program in which the information appeared won a 1986 Emmy award, and Janiger received a certificate honoring his contributions to the Emmy win.

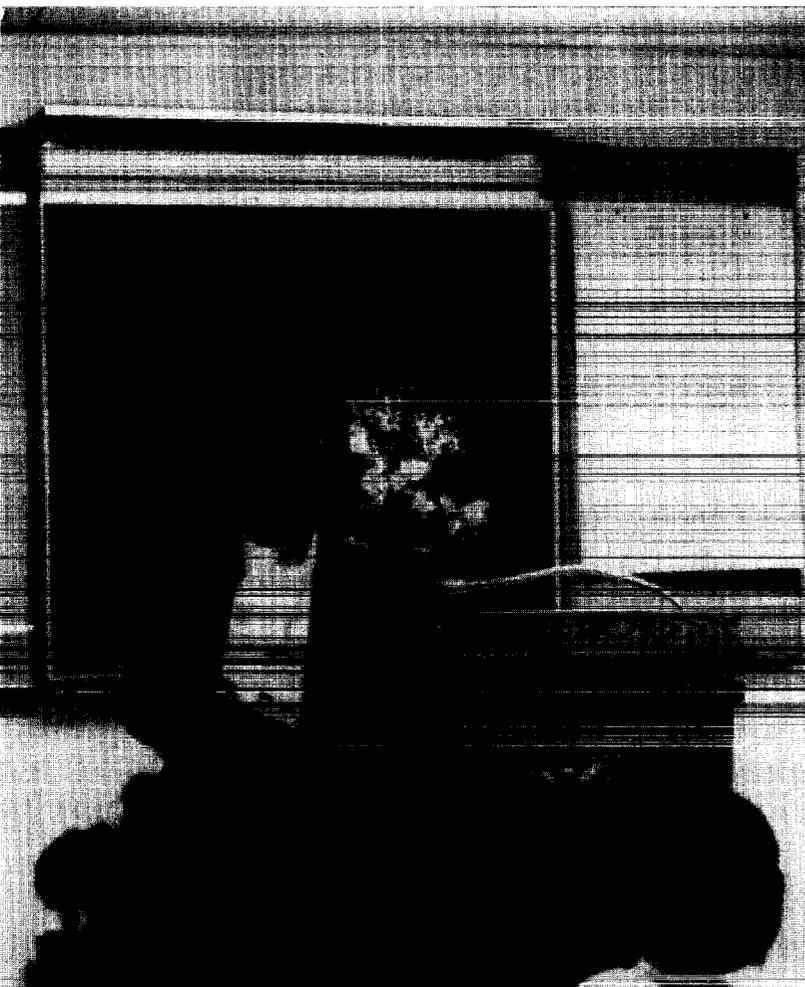
PAS's are in great demand to speak before all sorts of groups, and they agree

there are many tough audiences.

"For me, the toughest are groups of senior citizens," Janiger says. "Many of these people are retired, and they have the time—plus the inclination—to become very knowledgeable about



FDA's public affairs specialists often use broadcast media to reach the public. Here, New York City-based PAS Herman Janiger describes an FDA program on a local news show aired over New York's Channel One.



*FDA public affairs specialist
Barbara Miller explains
agency programs to a group
of New York City public
school students and faculty.*

health issues. And they have strong opinions on everything from dietary supplements to the pace of new product approvals. They keep me on my toes.”

Philadelphia PAS Theresa Holmes finds scientific and industry groups particularly challenging.

“Sometimes we have to shift gears in a hurry,” she says. “We may be translating science into lay terms for a consumer group one morning and then need to turn around and give a technical talk to scientists in the afternoon. Just call us ‘instant experts.’”

Although FDA’s PAS’s may vary widely in background and special

skills, they all share a “can do” attitude. Orlando PAS Lynn Isaacs recalls, when she was stationed in Minneapolis some years ago, driving through snow drifts to Fargo, N.D., to conduct a consumer exchange meeting to solicit views on FDA issues.

“We drove up to City Hall, and there were several sound trucks and TV cameras,” she recalls. “We wondered what was going on, thinking maybe a rock group was in town.”

Turns out the cameras were there to cover the meeting.

“We were really big in Fargo in January!” she laughs.

New York City PAS Barbara Miller also had to brave the elements in 1993 to deliver a presentation to a group of high school students learning how to become government employees.

“I arrived in a raging downpour,” she says. “I was trying to be very serious and professional, but my clothes were soaked and my hair was dripping all over the floor. As my hair dried, it frizzed up, and my wet shoes squeaked throughout the talk.”

The group, she felt, was especially attentive during her presentation.

“I think the kids were fascinated to see someone who’d come out in such conditions just to speak with them,” she says.

Among retiree Lois Meyer’s fondest memories are those of the 1969 White House Conference on Food, Nutrition, and Health. “This led to the first, early attempts at nutrition labeling,” she recalls, “which ultimately led to today’s new food label.

“We learned early on in the process that you can’t develop regulations in a vacuum,” she says. “You have to find out what the public wants and needs.”

Overall, Meyer remembers her FDA career as one with a heavy workload but many satisfactions.

“As a PAS, I believe I had an effect on a great many lives by teaching consumers,” she says. “Since the agency can’t be everywhere at once, it’s important for consumers to be educated. That’s where I came in, and the other PAS’s. We’re all different—women and men, young and older, culturally diverse—and bring different interests and skills to the job, but we have the most important things in common: dedication to FDA and a life-long interest in helping people.” ■

Betsy Adams is director of FDA’s press relations staff. John Henkel is a staff writer for FDA Consumer.

**A REPRINT FROM
FDA CONSUMER MAGAZINE**
Printed July 1995.

This article originally appeared in the
May 1995 *FDA Consumer*.

PUBLICATION NO. (FDA) 95-1222

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service Food and Drug Administration

We hope you found this reprint from *FDA Consumer* magazine useful and informative. *FDA Consumer*, the magazine of the U.S. Food and Drug Administration, provides a wealth of information on FDA-related health issues: food safety, nutrition, drugs, medical devices, cosmetics, radiation protection, vaccines, blood products, and veterinary medicine. For a sample copy of *FDA Consumer* and a subscription order form, write to: Food and Drug Administration, HFI-40, Rockville, MD 20857.

☆ U.S. GOVERNMENT PRINTING OFFICE 1995-386-968/20021

PUBLIC AFFAIRS
SPECIALIST
DIRECTORY

March 1999

NAME & TELEPHONE #	REGION/DISTRICT /ADDRESS	TERRITORIAL RESPONSIBILITY	INTERNET ADDRESS
<i>NORTHEAST REGION</i>			
Paula Fairfield (ext. 184) Joseph Raulinaitis (ext. 186) Susan Small (ext. 185) (781) 279-1675 FAX: (781) 279-1687	New England District One Montvale Avenue Stoneham, MA 02180	Connecticut Maine, Massachusetts New Hampshire Rhode Island Vermont	pfairfield@ora.fda.gov jraulina@ora.fda.gov ssmall@ora.fda.gov
Vacant (ext. 5754) Dilcia Granville (ext. 5043) Vincent Zuberko (ext. 5755) (718) 340-7000 FAX: (718) 340-7057	New York District 850 Third Avenue Brooklyn, NY 11232	New York City, Long Island (Nassau & Suffolk Counties) Westchester County & Rockland County	dgranvil@ora.fda.gov vzuberko@ora.fda.gov
Diana Monaco (ext. 3118) Debra Dathe (ext. 3101) (716) 551-4461 FAX: (716) 551-4470	Buffalo District 300 Pearl St., Suite 100 Olympic Towers Buffalo, NY 14202	All of New York (except Metro area (Albany, Binghamton, Champlain, Newburgh, Rochester & Syracuse))	monacod@ora.fda.gov ddathe@ora.fda.gov
<i>CENTRAL REGION</i>			
Joan G. Lytle (973) 526-6035 FAX: (973) 526-6069	New Jersey District Waterview Corporate Center 10 Waterview Blvd., 3 rd floor Parisippany, NJ 07054	New Jersey	jlytle@ora.fda.gov
Anitra Brown-Reed (215) 597-4390 FAX: (215) 597-6649	Philadelphia District Room 900 U.S. Customhouse 2 nd and Chestnut Streets Philadelphia, PA 19106	Delaware Pennsylvania	pas.phil@ora.fda.gov
Jeanni Prego (410) 962-3731 FAX: (410) 962-2307	Baltimore District 900 Madison Avenue Baltimore, MD 21201	Maryland, West Virginia Washington, DC, Virginia	jprego@ora.fda.gov

Marilyn Zipkes (ext. 110) (513) 679-2700 FAX: (513) 679-2771	Cincinnati District 6751 Steger Drive Cincinnati, OH 45237-3097	Kentucky Ohio	mzipkes@ora.fda.gov
Ruth Weisheit (330) 273-1038 FAX: (330) 225-7477	Brunswick Resident Insp. Post 3820 Center Road P.O. Box 838 Brunswick, OH 44212	Kentucky Ohio	rweishei@ora.fda.gov
Darlene Bailey (ext. 187) (312) 353-5863 FAX: (312) 886-3280 Kim Phillips	Chicago District 300 S. Riverside Plaza Suite 550-South Chicago, IL 60606	Illinois	dbailey@ora.fda.gov kphillip@ora.fda.gov
Evelyn DeNike (ext. 149) (313) 226-6158 Jane Cunningham (ext. 129) (313) 226-6260 FAX: (313) 226-3076 Linda Kettleon, PAT	Detroit District 1560 East Jefferson Avenue Detroit, MI 48207	Michigan	edenike@ora.fda.gov <i>jcunning@ora.fda.gov</i> lkettles@ora.fda.gov
Janet LeClair (ext. 13) Carol Gallagher (ext. 31) (317) 226-6500 FAX: (317) 226-6505	Indianapolis Resident Insp. Post 101 W. Ohio St., Suite 1300 Indianapolis, IN 46204	Indiana	jleclair@ora.fda.gov cgallagh@ora.fda.gov
Donald W. Aird (ext. 129) (612) 334-4100 FAX: (612) 334-4134	Minneapolis District 240 Hennepin Avenue Minneapolis, MN 55401	Minnesota North Dakota South Dakota	daird@ora.fda.gov
Steve Davis (ext. 19) Kathy Rozewicz (ext. 20) (414) 771-7167 FAX: (414) 771-7512	Milwaukee Resident Insp. Post 2675 N. Mayfair Rd, Suite 200 Milwaukee, WI 53226-1305	Wisconsin	sdavis@ora.fda.gov krozewicz@ora.fda.gov

<i>SOUTHEAST REGION</i>			
Nilda Villegas Ruth Marcano (787) 729-6852 FAX: (787) 729-6847	San Juan District Puerta de Tierra Station 466 Fernandez Juncos Avenue San Juan, PR 00901-3223	Puerto Rico Virgin Islands	nvillega@ora.fda.gov rmarcano@ora.fda.gov
JoAnn Pittman (ext. 5340) (404) 253-1272 FAX: (404) 253-1202	Atlanta District 60 Eighth Street NE Atlanta, GA 30309	Georgia South Carolina	jpittman@ora.fda.gov
Mary C. Lewis (ext. 17) (919) 856-4456 FAX: (919) 856-4776	Raleigh Resident Insp. Post 310 New Bern Avenue, Rm. 370 Raleigh, NC 27601	North Carolina	mlewis@ora.fda.gov
Lynne Isaacs (ext. 202) Faye Bronner (ext. 203) Frank Goodwin (ext. 221) (407) 475-4704 FAX: (407) 475-4769	Florida District 555 Winderley Place Suite 200 Maitland, FL 32751	Northern Florida	lisaacs@ora.fda.gov fbronner@fda.ora.gov fgoodwin@ora.fda.gov
Estela Niella-Brown (ext. 937) (305) 526-2800 FAX: (305) 526-2693	Miami Resident Insp. Post 6601 N.W. 25 th Street P.O. Box 59-2256 Miami, FL 33159-2256	South Florida (Miami, Palm Beach & Fort Myers	ebrown1@ora.fda.gov
Sandra Baxter (ext. 122) Mancia Davis (ext. 147) (615) 781-5372 FAX: (615) 781-5383	Nashville District 297 Plus Park Boulevard Nashville, TN 37217	Alabama, Tennessee	sbaxter@ora.fda.gov mdavis1@ora.fda.gov
Darlene Tollestrup (ext. 121) (504) 589-2420/2421 FAX: (504) 589-6360	New Orleans District 4298 Elysian Fields Avenue New Orleans, LA 70122	Louisiana Mississippi	dtollest@ora.fda.gov

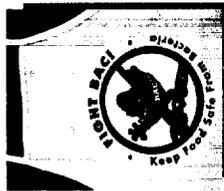
<i>SOUTHWEST REGION</i>			
Maria Velasco (ext. 308) Helen Monda (ext. 303) (214) 655-5315. FAX: (214) 655-5331	Dallas District 3310 Live Oak Street Dallas, TX 75204	Dallas & Ft. Worth, TX; and all of Oklahoma	mvelasco@ora.fda.gov hmonda@ora.fda.gov
Sheryl Lunnon-Baylor (ext. 15) (713) 802-9095 FAX: (713) 802-0906	Houston Resident Insp. Post 1445 N. Loop West – Suite 420 Houston, TX 77008	Houston Metro area, Eastern Texas (Beaumont, Galveston) and all of Arkansas	sbaylor@ora.fda.gov
Vacant (ext. 13) (210) 229-4531 FAX: (210) 229-4548	San Antonio Resident Insp. Post 10127 Morocco - Suite 119 San Antonio, TX 78216	South Central Texas (Amarillo, Lubbock, Waco, Austin, San Antonio, El Paso, Laredo, Hidalgo and Brownsville	
Tywanna Paul (913) 752-2141 FAX: (913) 752-2111	Kansas City District 11630 W. 80 th Street Lenexa, KS 66214	All of Kansas and Nebraska - Including Kansas City, MO metro area. Omaha/Council Bluff, IA metro area.	tpaul@ora.fda.gov
Mary-Margaret Richardson (ext. 123) (314) 645-1167 FAX: (314) 645-2969	St. Louis Branch 12 Sunnen Drive, Suite 122 St. Louis, MO 63143	All of Missouri except Kansas City and all of Iowa	mrichard@ora.fda.gov
Virlie Walker (303) 236-3018 Devin Koontz (303) 236-3020 FAX: (303) 236-3551	Denver District Denver Federal Center Building 20, Room B-1121 6 th Avenue and Kipling Denver, CO 80225-0087	All Colorado, New Mexico, Utah and Wyoming	vwalker@ora.fda.gov dkoontz@ora.fda.gov

PACIFIC REGION			
Janet McDonald (510) 337-6845 Mary Ellen Taylor (510) 337-6888 FAX: (510) 337-6708	San Francisco District 1431 Harbor Bay Parkway Alameda, CA 94502-7070	Northern California (Fresno, Sacramento, San Jose, Guam and Stockton), Nevada and the Pacific rim territories (Guam)	jmcdonal@ora.fda.gov mtaylor1@ora.fda.gov
Rosario Quintanilla Vior (949) 798-7607 Laurel Eu (949) 798-7609 FAX: (949) 798-7715	Los Angeles District 19900 MacArthur Blvd., Suite 300 Irvine, CA 92715-2445	Southern California (Calexico, Canoga Irvine, Los Angeles, San Diego, San Ysidro, Santa Barbara, Rancho Cucamonga and Terminal Island	rqvior@ora.fda.gov leu@ora.fda.gov
Gilbert V. Meza (ext. 225) (602) 829-7396 FAX: (602) 829-7677	Phoenix Resident Insp. Post 4605 East Elwood St., Suite 402 Phoenix, AZ 85040-1948	All of Arizona	gmeza@ora.fda.gov
Susan Hutchcroft (425) 483-4953 FAX: (425) 483-4996	Seattle District 22201 23 rd Drive, S.E. Bothell, WA 98201-4421	All of Washington State and Alaska	shutchr@ora.fda.gov
Alan Bennett (ext. 22) (503) 671-9332 FAX: (503) 671-9445	Portland Resident Insp. Post 9780 S.W. Nimbus Avenue Beaverton, OR 97008-7163	Oregon, Idaho and Montana	abennett@ora.fda.gov



A. CERAMIC MUG

11-ounce white ceramic mug with four-color Fight BAC!™ logo on two sides. Price: \$8.00 each.



B. APRON

21" white, pocketed, tie-back apron with four-color Fight BAC!™ logo. Price \$10.00 each.



C. EMBLEMS

1" embroidered, removable appliqué with four-color Fight BAC!™ logo. Price: \$1.25 each (10 minimum)



D. MAGNETS

3" x 4" four-color magnet with the four quadrants encompassing the Fight BAC!™ logo.

Price: \$.75 each (25 minimum)

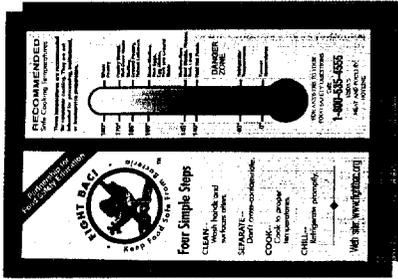
Visit our website for publication materials including Fight BAC!™ English and Spanish brochures, Community Action Kits, Presenter's Guides and more. To order, see "Spread the Word" icon at www.fightbac.org online.



E. STICKERS

2" diameter four-color sticker with Fight BAC!™ logo.

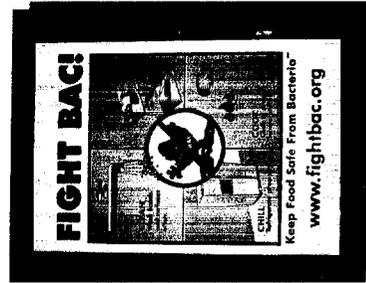
Price: \$50.00 per roll of 500. (1 Roll)



F. BOOKMARKS

7.5" x 2.5" four-color bookmark with Fight BAC!™ logo and safe food handling instructions (thermometer). Both sides printed.

Price: \$.75 each. (10 minimum)



G. POSTERS

19" x 27" four-color varnished poster with the four quadrants encompassing the Fight BAC!™ logo.

Price: \$1.00 each (10 minimum)

The Partnership
for
Food Safety Education



FIGHT BAC!™
STORE

1999

**B A C K G R O U N D E R**

CURRENT & USEFUL INFORMATION FROM THE FOOD & DRUG ADMINISTRATION

Food Safety: A Team Approach

September 24, 1998

The United States maintains one of the world's safest food supplies, thanks in large part to an interlocking monitoring system that watches over food production and distribution at every level-locally, statewide and nationally.

Continual monitoring is provided by food inspectors, microbiologists, epidemiologists, and other food scientists working for city and county health departments, state public health agencies, and various federal departments and agencies. Their precise duties are dictated by local, state and national laws, guidelines and other directives. Some monitor only one kind of food, such as milk or seafood. Others work strictly within a specified geographic area. Others are responsible for only one type of food establishment, such as restaurants or meat-packing plants. Together they make up the U.S. food safety team.

The Clinton administration's Food Safety Initiative, begun in 1997, strengthens the efforts of all the members of the nation's food safety team in the fight against food-borne illness, which afflicts between 6.5 million and 33 million Americans every year. One of the initiative's major programs got under way in May 1998 when the Department of Health and Human Services (which includes FDA), the U.S. Department of Agriculture, and the Environmental Protection Agency signed a memorandum of understanding to create a Food Outbreak Response Coordinating Group, or FORC-G. The new group will:

- increase coordination and communication among federal, state and local food safety agencies
- guide efficient use of resources and expertise during an outbreak
- prepare for new and emerging threats to the U.S. food supply.

Besides federal officials, members of FORC-G include the Association of Food and Drug Officials, National Association of City and County Health Officials, Association of State and Territorial Public Health Laboratory Directors, Council of State and Territorial Epidemiologists, and National Association of State Departments of Agriculture.

The following table offers a closer look at the nation's food safety lineup. The agencies listed in the table also work with other government agencies, such as the Consumer Product Safety Commission to enforce the Poison Prevention Packaging Act, the FBI to enforce the Federal Anti-Tampering Act, the Department of Transportation to enforce the Sanitary Food Transportation Act, and the U.S. Postal Service to enforce laws against mail fraud.

U.S. Department of Health and Human Services *

Food and Drug Administration

Oversees

- All domestic and imported food sold in interstate commerce, including shell eggs, but not meat and poultry
- Bottled water
- Wine beverages with less than 7 percent alcohol

Food Safety Role

Enforces food safety laws governing domestic and imported food, except meat and poultry, by:

- Inspecting food production establishments and food warehouses and collecting and analyzing samples for physical, chemical and microbial contamination
- Reviewing safety of food and color additives before marketing
- Reviewing animal drugs for safety to animals that receive them and humans who eat food produced from the animals
- Monitoring safety of animal feeds used in food-producing animals
- Developing model codes and ordinances, guidelines and interpretations and working with states to implement them in regulating milk and shellfish and retail food establishments, such as restaurants and grocery stores. An example is the model Food Code, a reference for retail outlets and nursing homes and other institutions on how to prepare food to prevent food-borne illness.
- Establishing good food manufacturing practices and other production standards, such as plant sanitation, packaging requirements, and Hazard Analysis and Critical Control Point programs
- Working with foreign governments to ensure safety of certain imported food products
- Requesting manufacturers to recall unsafe food products and monitoring those recalls
- Taking appropriate enforcement actions
- Conducting research on food safety
- Educating industry and consumers on safe food handling practices

For More Information

Consumers:

FDA Headquarters

Office of Consumer Affairs

HFE-88

5600 Fishers Lane

Rockville, MD 20857

Regional FDA offices, listed in the blue pages of the phone book under U.S. Government

Media inquiries: 202-205-4144

Consumers:

FDA's Food Information and Seafood Hotline

1-800-FDA-4010 (1-800-332-4010),

202-205-4314 in the Washington, D.C., area

www.cfsan.fda.gov/list.html

www.fda.gov/cvm/

Centers for Disease Control and Prevention

Oversees

- All foods

Food Safety Role

- Investigates with local, state and other federal officials sources of food-borne disease outbreaks
- Maintains a nationwide system of food-borne disease surveillance: Designs and puts in place rapid, electronic systems for reporting food-borne infections. Works with other federal and state agencies to monitor rates of and trends in food-borne disease outbreaks. Develops state-of-the-art techniques for rapid identification of food-borne pathogens at the state and local levels.
- Develops and advocates public health policies to prevent food-borne diseases
- Conducts research to help prevent food-borne illness
- Trains local and state food safety personnel

For More Information

Centers for Disease Control and Prevention
1600 Clifton Rd., N.E.
Atlanta, GA 30333

Media inquiries: 404-639-3286

General public: 404-639-3311

www.cdc.gov

* Also, HHS's National Institutes of Health conduct food safety research.

U.S. Department of Agriculture **

Food Safety and Inspection Service

Oversees

- Domestic and imported meat and poultry and related products, such as meat- or poultry-containing stews, pizzas and frozen foods
- Processed egg products (generally liquid, frozen and dried pasteurized egg products)

Food Safety Role

Enforces food safety laws governing domestic and imported meat and poultry products by:

- Inspecting food animals for diseases before and after slaughter
- Inspecting meat and poultry slaughter and processing plants
- With USDA's Agricultural Marketing Service, monitoring and inspecting processed egg products
- Collecting and analyzing samples of food products for microbial and chemical contaminants and infectious and toxic agents
- Establishing production standards for use of food additives and other ingredients in preparing and packaging meat and poultry products, plant sanitation, thermal processing, and other processes
- Making sure all foreign meat and poultry processing plants exporting to the United States meet U.S. standards
- Seeking voluntary recalls by meat and poultry processors of unsafe products
- Sponsoring research on meat and poultry safety
- Educating industry and consumers on safe food-handling practices

For More Information

FSIS Food Safety Education and Communications Staff
Room 1175, South Building,
1400 Independence Ave., S.W.
Washington, DC 20250

Media inquiries: 202-720-9113

Consumers:
The Meat and Poultry Hotline, 1-800-535-4555
(In Washington, D.C., area, call 202-720-3333.)
TDD/TTY: 1-800-256-7072

www.fsis.usda.gov

Cooperative State Research, Education, and Extension Service

Oversees

- All domestic foods, some imported

Food Safety Role

- With U.S. colleges and universities, develops research and education programs on food safety for farmers and consumers

For More Information

Local cooperative extension services, listed in the blue pages of the phone book under county government

Cooperative State Research, Education and Extension Service
U.S. Department of Agriculture
Washington, DC 20250-0900
202-720-3029

www.reeusda.gov

National Agricultural Library USDA/FDA Foodborne Illness Education Information Center

Oversees

- All foods

Food Safety Role

- Maintains a database of computer software, audiovisuals, posters, games, teachers' guides and other educational materials on preventing food-borne illness
- Helps educators, food service trainers and consumers locate educational materials on preventing food-borne illness

For More Information

USDA/FDA Foodborne Illness Education Information Center
Food and Nutrition Information Center
National Agricultural Library/USDA
Beltsville, MD 20705-2351

301-504-5719

www.nal.usda.gov/fnic/

** Also, a number of other USDA agencies conduct food safety activities.

U.S. Environmental Protection Agency

Oversees

- Drinking water

Food Safety Role

Foods made from plants, seafood, meat and poultry

- Establishes safe drinking water standards
- Regulates toxic substances and wastes to prevent their entry into the environment and food chain
- Assists states in monitoring quality of drinking water and finding ways to prevent

contamination of drinking water

- Determines safety of new pesticides, sets tolerance levels for pesticide residues in foods, and publishes directions on safe use of pesticides

For More Information

Environmental Protection Agency
401 M St., S.W.
Washington, DC 20460

202-260-2090

Regional EPA offices, listed in the blue pages of the phone book under U.S. Government

www.epa.gov

U.S. Department of Commerce

National Oceanic and Atmospheric Administration

Oversees

- Fish and seafood products

Food Safety Role

- Through its fee-for-service Seafood Inspection Program, inspects and certifies fishing vessels, seafood processing plants, and retail facilities for federal sanitation standards

For More Information

Seafood Inspection Program
1315 East-West Highway
Silver Spring, MD 20910

1-800-422-2750

www.nmfs.gov/iss/services.html

U.S. Department of the Treasury

Bureau of Alcohol, Tobacco and Firearms

Oversees

- Alcoholic beverages except wine beverages containing less than 7 percent alcohol

Food Safety Role

- Enforces food safety laws governing production and distribution of alcoholic beverages

- Investigates cases of adulterated alcoholic products, sometimes with help from FDA

For More Information

Bureau of Alcohol, Tobacco and Firearms
Market Compliance Branch
650 Massachusetts Ave., N.W.
Room 5200
Washington, DC 20226

202-927-8130

www.atf.treas.gov/core/alcohol/alcohol.htm

U.S. Customs Service

Oversees

- Imported foods

Food Safety Role

- Works with federal regulatory agencies to ensure that all goods entering and exiting the United States do so according to U.S. laws and regulations

For More Information

U.S. Customs Service
P.O. Box 7407
Washington, DC 20044

Media inquiries: 202-927-1770

General public: Contact local ports of entry, listed in the blue pages of the phone book under U.S. Government, Customs Services

www.customs.ustreas.gov

U.S. Department of Justice

Oversees

- All foods

Food Safety Role

- Prosecutes companies and individuals suspected of violating food safety laws
- Through U.S. Marshals Service, seizes unsafe food products not yet in the marketplace, as ordered by courts

For More Information

U.S. attorneys' offices in blue pages of phone book under U.S. Government

www.usdoj.gov

Federal Trade Commission

Oversees

- All foods

Food Safety Role

- Enforces a variety of laws that protect consumers from unfair, deceptive or fraudulent practices, including deceptive and unsubstantiated advertising.

For More Information

FTC (Federal Trade Commission)
Consumer Response Center, CRC-240
Washington, DC 20580

Media inquiries: 202-326-2180
TDD: 202-326-2502

Consumers: 202-FTC-HELP
(202-382-4357)

www.ftc.gov

State and Local Governments

Oversees

- All foods within their jurisdictions

Food Safety Role

- Work with FDA and other federal agencies to implement food safety standards for fish, seafood, milk, and other foods produced within state borders
- Inspect restaurants, grocery stores, and other retail food establishments, as well as dairy farms and milk processing plants, grain mills, and food manufacturing plants within local jurisdictions
- Embargo (stop the sale of) unsafe food products made or distributed within state borders

For More Information

City, county and state health, agriculture and environmental protection agencies, listed in the blue pages of the phone book under city, county and state government

EVALUATION OF FDA VIDEO TELECONFERENCE
APRIL 28, 1999

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders?

As a new participant (teacher)
this was a ~~good~~ learning experience.

Broadcast length?

The time period was very appropriate.

Broadcast format? (conversations with Drs. Henney and Suydam; use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

Would have liked the question origin (city) to have been identified as well.
Style of questioning was fine.

Subject matter covered?

Subject matter was fine.

Usefulness to stakeholders?

I look forward to its use
in my field of education.

EVALUATION OF FDA VIDEO TELECONFERENCE

APRIL 28, 1999

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders? Good job! Well publicized about meeting time, etc. Good to have opportunity to see program & participate at ~~total~~ local level.

Broadcast length? Good.

Broadcast format? (conversations with Drs. Henney and Suydam, use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

Liked related, "talk show" style. Studio audience participation creates bias.

Subject matter covered? The key questions were to be focused upon & they were met.

Usefulness to stakeholders? Useful but goal not met. Goal was to get suggestions on 6 key areas.

EVALUATION OF FDA VIDEO TELECONFERENCE
APRIL 28, 1999

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders?

Very accessible

Broadcast length?

Could have been shorter

Broadcast format? (conversations with Drs. Henney and Suydam; use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

Very informative

Subject matter covered?

Adequate

Usefulness to stakeholders?

Informative

EVALUATION OF FDA VIDEO TELECONFERENCE
APRIL 28, 1999

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders? Good

Broadcast length? Good -

Broadcast format? (conversations with Drs. Henney and Suydam, use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

Talk show style adequate for this topic.

Subject matter covered? Seemed to be very general & not too specific. No commitment to specific questions

Usefulness to stakeholders? Good.

**EVALUATION OF FDA VIDEO TELECONFERENCE
APRIL 28, 1999**

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders?

OK

Broadcast length?

good time

Broadcast format? (conversations with Drs. Henney and Suydam, use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

format / very well done

Subject matter covered?

Very informative but not for the general public

Usefulness to stakeholders?

Very good over-all. Again the need to address the general public - less scientific and more direct on the how to or how do you do? or How has the part been created?

**EVALUATION OF FDA VIDEO TELECONFERENCE
APRIL 28, 1999**

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders?

Excellent environment to have discussions that effects patients/providers

Broadcast length?

Needs more time for Q+A and interaction with Deputy Directors

Broadcast format? (conversations with Drs. Henney and Suydam, use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

Format needs

Subject matter covered?

So much to cover in so little time

Usefulness to stakeholders?

Opportunity to network together over common interest

Good Job!!

**EVALUATION OF FDA VIDEO TELECONFERENCE
APRIL 28, 1999**

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders?

Excellent! I asked for and received accommodation (sep. viewing room) for sensitivity to fragrances often found in groups. I appreciate the kind treatment I received from Mr. Pittman, Mr. Arto and others.

Broadcast length?

good

Broadcast format? (conversations with Drs. Henney and Suydam, use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

Good format.

Good moderator.

Dr. Henney seems remarkably informed.

Subject matter covered?

No issues regarding cosmetics or fragrances regulation were mentioned. Drug issues predominated.

Usefulness to stakeholders?

It disturbs me that the taped teleconference will contain absolutely no mention of the fragranced products that are of concern to myself and others, as if they do not fall under FDA jurisdiction or are of no interest to the FDA whatsoever.

EVALUATION OF FDA VIDEO TELECONFERENCE
APRIL 28, 1999

To help us plan for future stakeholder activities, we want your comments on today's teleconference. Please fill out this form and leave it with the FDA coordinator at your downlink site.

Accessibility to stakeholders?

Good if you are in a regional city

Broadcast length?

Good

Broadcast format? (conversations with Drs. Henney and Suydam, use of studio audience, use of "talk show" style, phoned and faxed questions, etc.)

Good. TV Needs to be higher up hard to see

Subject matter covered?

Good - Give the deputy directors more time to speak re Specifics vs. Generalizations from Commissioners

Usefulness to stakeholders?

↳ Yes.