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Domestic Policy Council

Box 4 of 4

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West Nile
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VICE PRESIDENT GORE ANNOUNCES NEW MEASURES TO INCREASE THE SAFE USE OF OVER THE COUNTER MEDICATIONS

March 12, 1999

Today, Vice President Gore is unveiling a ^{a final} ~~historical~~ new FDA regulation that, ^{reformats/reinvents the labels} for the first time, ~~requires~~ over-the-counter drug products to use a new product label with larger print and clearer language, making it easier for consumers to understand product warnings and comply with dosage guidance. The Vice President also announced that this spring, FDA will ^{also} launch a new national public information campaign to ^{help} educate consumers ^{learn more about over-the-counter drugs.} about the information provided by the new labels. This new regulation and campaign provides Americans critical information about medications and will ^{help} prevent the tens of thousands of unnecessary hospitalizations caused by misuse of over-the-counter medications each year.

^{in a much more user-friendly way} be an important step toward preventing
MISUSE OF OVER-THE-COUNTER MEDICATIONS IS COMMON AND POTENTIALLY DANGEROUS

- **More and more Americans use of over-the-counter medications to treat routine illnesses.** Each year, Americans purchase five billion over-the-counter drug products for a wide variety of ailments, from headaches to arthritis to sore throats. Approximately 100,000 over-the-counter drugs can be used to treat routine illnesses without a prescription, ^{allowing} requiring the consumer to make their own judgement about what drug to take, how to take it, and whether or not to give it to their children.

- **Misusing over-the-counter drugs can be dangerous.** ^{health care} The misuse of over-the-counter ^{although over-the-counter drugs are generally very safe,} drugs causes over 170,000 hospitalizations each year at an annual cost of \$750 million. Studies estimate that half of these hospitalizations could have been prevented by better consumer education and information. These unacceptably high hospitalization rates underscore how important it is that consumers ~~be able to~~ understand the information and recommendations in drug product labeling.

- **Current labeling ^{design, format, and placement of} has put consumers at risk, particularly the elderly and children.** ^{is often difficult to read and understand} The current required labeling information varies considerably among over-the-counter drug products. As a result, consumers often have difficulty finding, reading, and understanding critical information about these products. ^{* FDA} One study reported that only 30 percent of caregivers were able to measure the correct dose of medication for their child, indicating that many parents may be at risk of administering an overdose to their children. In addition, older people, who take more over-the-counter medications, are at increased risk of taking the wrong dose of a medication or of taking an over-the-counter medication that adversely interacts with a prescription medication they are taking because they often have difficulty reading the product label. ^{Studies have shown that a significant number of found older Americans can not read the small, compressed type on many products today, and these individuals are at face a greater risk of misusing these products.}
- PROVIDING CONSUMERS WITH CRITICAL INFORMATION ABOUT OVER-THE-COUNTER DRUG PRODUCTS.** Today, the Vice President announced:

- ^{FDA} ~~new~~ regulations providing new, ^{easy to understand} and labeling for over-the-counter drugs. The ^{new} FDA regulation provides consumers with the essential information ^{new labeling that will aim to provide}

~~The sign of the point, however, is not the~~ Others with normal vision also report having difficulty reading the labeling because of the way the information is presented and may have difficulty picking the right product to treat their condition.

necessary for them to make informed decisions about their health care. The new label for over-the-counter drug product:

- ^a **Requires standardized, easy-to-follow format.** The regulation requires labels to ~~include~~ ^{present} ingredients in the very same place on every product and to explain their specific purposes in a given product in order to indicate which ingredients are used to treat specific symptoms; and ~~important information such as the product's active ingredients, uses, warnings and directions to be presented~~ ^{standardized headings and subheadings} in the same format and order.
- **Includes critical information about the drug product.** The regulation clearly ~~presents a drug's ingredients, dose, and warnings, making it easier for consumers to find and understand essential information about the medication's expected effectiveness and associated risks, and to compare the labeling of different products;~~ ^{making}
- ^{Specifies a minimum type size for the label} **Increases the size of the label so they can be easily read.** The regulation ^{specifies} increases the minimum type size for labels in order to make ^{them} it easier to read. ^{based specifically on studies that included older people.}

This new label, which applies to all 100,000 over-the-counter drugs and drug cosmetics, will begin to appear on ~~some of these~~ ^{new} products within the next ~~six weeks~~ ^{30 days} and will appear on all of them within the next ~~two~~ ^{years}. FDA is also recommending that drug manufacturers include a phone number for consumers to call if they have questions about the product.

- **A new public information campaign to teach consumers how to use the new labels.** The Vice President announced that this spring, the FDA will launch a new, \$----- public education campaign to help consumers ^{better} understand ^{how} to use ~~easy-to-read labels~~ to learn more about over-the-counter medications and to encourage them to ask to their health care providers questions about their medications. This campaign, which targets the elderly, child care providers, and health professionals, will include ~~the publication of~~ public service announcements in newspapers and magazines, radio PSAs to be broadcast [where?], and the distribution of brochures and posters on the new labels through professional organizations, such as the National Association of Chain Drug Stores and the Nonprescription Drug Manufacturers Association.
- **Awarded FDA with a "plain language" award for these new improvements.** As part of his reinventing government initiative, the Vice President also gave the FDA a plain language award for developing a clear new format. [NPR to add language.]

- Allows for a modified format for small packages. The regulation allows ~~for~~ a modified format for packages that are too small to include the standardized "Drug Facts" box.



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Title

Over-the-counter medications. Do parents give what they intend to give? [see comments]

Author

Simon HK; Weinkle DA

Address

Department of Pediatrics, Egleston Children's Hospital, Emory University School of Medicine, Atlanta, Ga., USA.
hsimon@emory.edu

Source

Arch Pediatr Adolesc Med, 1997 Jul, 151:7, 654-6

Abstract

OBJECTIVE: To evaluate caregiver (parent or guardian) use of over-the-counter medications (OTCs) as related to the accuracy and correctness of dosing for children seen at a pediatric emergency department with nonemergent concerns. **DESIGN:** Prospective patient series. **SETTING:** A tertiary care pediatric emergency center. **PARTICIPANTS:** A representative sample of children with nonemergent chief complaints. **INTERVENTIONS:** A questionnaire about general demographic characteristics, recent OTC use, and medical history of the patients was given to each caregiver. A mock scenario was then presented that required the caregivers to determine and measure a correct dose of acetaminophen for their child. A dose of 9 to 16.5 mg/kg was considered correct. Accuracy of measuring was considered within +/-20% of the caregivers' stated intended dose for their child. **RESULTS:** One hundred caregivers were enrolled in the study. Mean caregivers' age was 29 years, with 82% having at least a high school education. Seventy-seven percent of their children used OTCs within the previous 2 months, and Tylenol (acetaminophen) was the most commonly used. While 66% of the caregivers reported Tylenol use, only 8% reported the use of acetaminophen. During the dosing scenario, only 40% of the caregivers stated an appropriate dose for their child and only 67% accurately measured the amount of acetaminophen they intended. Forty-three percent measured out a correct amount of acetaminophen for their child. However, almost one third of these occurred strictly by accident because they inaccurately measured an improper intended dose. Combining these results, only 30% of the caregivers were able to

demonstrate both an accurately measured and correct dose for their child. **CONCLUSIONS:** Although a large number of caregivers administer OTCs, knowledge of these medications, and accuracy and correctness of dosing remain a marked concern. Improved caregiver education on the accuracy and correctness of dosing OTCs is necessary.

Language of Publication

English

Unique Identifier

97375783

[Order full text for this document](#)**MeSH Heading (Major)**

Drugs, Non-Prescription|*AD; Medication Errors|*; Parents|*

MeSH Heading

Acetaminophen|AD; Adult; Analgesics, Non-Narcotic|AD; Child; Female; Fever|DT; Health Education; Human; Male

Publication Type

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HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

P94-21
FOR IMMEDIATE RELEASE
Dec. 13, 1994

Food and Drug Administration
Don McLearn (301) 443-1130
Home (301) 926-6909

FDA ANNOUNCES NEW RULES FOR CHILDREN'S MEDICINES

The Food and Drug Administration today announced new steps to provide health care professionals with the information necessary to prescribe medications more safely for children.

The new measures announced today are designed to eliminate unnecessary risks faced by children and adolescents aged 16 and under when treated with drugs primarily tested in adults. The vast majority of prescription drugs currently on the market lack information about appropriate use in children.

A key element is amending a 1979 regulation that required full clinical trials in the pediatric population as a basis for labeling for use in children. That rule is being amended to allow companies, in some situations, to extrapolate from adult studies and use that information -- along with other information about use of the drug in children -- to provide labeling information on the appropriate use in children.

"Taking care of our children is our top priority," said HHS Secretary Donna E. Shalala. "These measures promise the kind of quality medical care our children deserve."

FDA Commissioner David A. Kessler, M.D., a pediatrician, proposed this rule change in a speech to the American

-MORE-

ATTENTION: PLEASE USE OPEN CAPTIONING FOR THE HEARING IMPAIRED.

Page 2, P94-21, Pediatric Labeling Academy of Pediatrics in October 1992. In addition to the final rule change announced today, FDA's Center for Drug Evaluation and Research is taking steps to increase the number of pediatric studies included in submissions for new prescription medicines.

"We have a duty to our children," said Kessler. "We can get the information we need to treat our children safely and effectively if we think creatively and are willing to commit resources to the challenge."

The new rule, being announced in the Federal Register today, revises the "Pediatric Use" subsection of prescription drugs labeling and makes it easier, in some situations, for manufacturers to include pediatric information on the label of their prescription products.

One of the rule's key provisions sets forth the conditions under which the agency permits pediatric use statements based on adequate and well-controlled studies in adults together with other information, such as pharmacokinetic and safety data, that supports pediatric use.

The rule makes clear that such pediatric use statements can be made only if the course of the disease and the drug's effects are sufficiently similar in the pediatric and adult populations to permit extrapolation from the adult data to pediatric patients.

Under the new rule, manufacturers also must reexamine existing information to determine whether the pediatric labeling of their marketed products can be modified on the basis of adult studies and

-MORE-

Page 3, P94-21, Pediatric Labeling

other available data. If so, they have to submit an application for supplemental labeling within two years.

Finally, the new regulation clarifies that the agency has the authority to request specific pediatric use information. For example, FDA may decide to request pediatric use data for a drug that is widely used, represents a safety hazard or is therapeutically important in the pediatric population. The rule, however, does not limit the manner in which a practitioner may prescribe an approved drug.

The additional measures will include the establishment of a special pediatric subcommittee that will track the implementation of the new regulations and draft policies and guidance documents to ensure that the possibility of pediatric testing and use are explored during the development of new drugs.

The agency also will work closely with the Pediatric Pharmacology Research Units that are funded by the National Institute of Child Health and Human Development to conduct pediatric studies on selected therapies. Finally, FDA will work with sponsors on investigational new drug applications and on new marketing applications to ensure that necessary pediatric data are included for products that have a potentially widespread use in children.

FDA is one of the Public Health Service agencies within HHS.

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THE WALL STREET JOURNAL

FRIDAY, NOVEMBER 15, 1996 B1

In the Line for AIDS Drugs, Children Are Last

By LAURIE MCGINLEY

Staff Reporter of THE WALL STREET JOURNAL

The revolutionary drug therapies helping many adult AIDS patients are unavailable to most infected children.

None of the three protease inhibitors prescribed for adults — Roche Holding Ltd.'s Invirase, Abbott Laboratories' Norvir and Merck & Co.'s Crixivan — has been

MEDICINE

tested widely in children. Lacking pediatric data, the Food and Drug Administration hasn't cleared the drugs for use in children. While doctors can legally prescribe a drug for a child without such clearance if it has been approved for use by adults, many won't do so in the case of the protease inhibitors because of a paucity of information. They worry that incorrect use of the drugs could be harmful or make it difficult for a child to use a better, yet-to-be-developed medication.

"I'm frustrated," says Ann Petru, director of the pediatric AIDS program at Children's Hospital Oakland in California. "I don't have any dosing information. I have no idea what is a safe dose or a toxic one."

One of her patients is nine-year-old Samuel Fox of Newark, Calif. While Samuel appears healthy — playing soccer, scrapping with his older brother — tests show that the amount of virus in his blood is six times higher than it was in March. His mother, Marilyn, wants Samuel, who

Mostly Out of Reach

BRAND NAME	MANUFACTURER	APPROVAL DATE
Relovir	Glaxo Wellcome	Adults, 1987; infants and children, 1989
Videx	Bristol-Myers Squibb	Adults and children, Oct. 1991
Hivid	Roche Holding	Adults only, June 1992
Zerit	Bristol-Myers Squibb	Adults only, June 1994
Epivir	Glaxo Wellcome	Adults, children and infants, Nov. 1995
Invirase*	Roche Holding	Adults only, Dec. 1995
Norvir*	Abbott Laboratories	Adults only, March 1996
Crixivan*	Merck & Co.	Adults only, March 1996
Viramune	Bioehringer Ingelheim	Adults only, June 1996

*Protease inhibitors

Sources: Pediatric AIDS Foundation; Food and Drug Administration

is adopted, to start taking a protease inhibitor. "It just scares the hell out of me that I'm going to lose him," she says. But Dr. Petru wants more information about the drugs before she considers putting him on one of the new drugs.

Of the three protease inhibitors, Roche Holding's Invirase was approved for adults last December; Abbott Laboratories' Norvir and Merck's Crixivan were cleared early this year. Studies in adults showed that the protease inhibitors, when combined with existing AIDS drugs, were the most potent anti-AIDS weapons yet devised.

Teenagers with AIDS are routinely treated with the new drugs, but only the sickest of the younger children or those in small-scale clinical trials are getting them.

Newborns aren't getting the drugs at all. Heightening the frustration of pediatricians and parents is the fact that some of these trials suggest that the protease inhibitors may be of great benefit to infected children. Just last week, for example, the National Cancer Institute reported that, in a small study of children aged six months to 14 years, Abbott's drug is safe and appears to have "a significant antiviral effect."

"There is such a feeling of optimism and hope among adults, but it hasn't yet been translated into hope for children," says Michael Kalser, a New Orleans doctor who works with people with AIDS.

How did this happen?

The fact is that the protease inhibitors are part of a larger picture: Only about 20%

of all drugs approved for use in the U.S. have been tested in children and have had labeling information about their pediatric use approved by the FDA, says Susan DeLaurentis, co-founder and chief executive officer of the Pediatric AIDS Foundation, which is based in Santa Monica, Calif. Of the nine AIDS drugs that have been approved for adults over the last decade, only three have also been approved for pediatric use: AZT, ddI and 3TC.

In the case of the protease inhibitors, critics contend that drug companies have been slow to develop pediatric data because children make up only a small proportion of infected individuals. Since 1981, more than 7,200 children aged 12 and under have been diagnosed with AIDS in the U.S., compared with more than 548,000 adults, according to the Centers for Disease Control and Prevention. "The attitude of the drug companies is that it's not economically feasible or profitable because there is a limited number of infected children," asserts Dianne Donovan, a resident of Queensbury, N.Y., who adopted two children who are HIV-positive.

Abbott, in particular, comes in for tough criticism. Because Norvir was initially developed as a liquid, making it readily ingestible by infants and small children, it "was the one that could have been pushed into pediatric studies at a much earlier stage," says Philip Pizzo, a leading AIDS researcher who is physician in chief and chairman of the department of

Please Turn to Page B9, Column 1

In Line for Medicines Used to Treat AIDS, Children Come Last

Continued From Page B1

medicine at Children's Hospital in Boston. "But the company simply didn't push hard to put pediatric studies in place."

Abbott officials vehemently deny that they acted too slowly or that the small size of the pediatric market has influenced their priorities. They say they have followed the prudent course of testing the drug extensively on adults first. "We go through a careful process where adults, who can give their consent, can participate; and once we have the information from adults, we can take it to the children," says John Leonard, the head of Abbott's antiviral venture. Abbott has begun having preliminary talks with the FDA about adding recommended doses for children on Norvir's label, and the company hopes it will get the go-ahead before long.

Merck and Roche are further behind. Merck officials say they are moving as quickly as they can to develop a liquid that young children can take, but have encountered frustrating obstacles involving taste and the way the drug is absorbed in the body. Roche is working on a powder-like pediatric version of Invirase that can be sprinkled into a child's milk or formula bottle. All three protease makers say they are proceeding quickly by historical standards; in any case, various studies involving larger numbers of children are likely to begin later this year or early next year.

Two other drug companies that are working on new protease inhibitors, Agouron Pharmaceuticals Inc. and Glaxo Wellcome PLC, plan to seek FDA approval for use by children at the same time they seek approval for use by adults. On another front, researchers at the University of Massachusetts Medical Center have gotten encouraging results in tests involving infants given a new mixture of drugs not including any protease inhibitor.

FDA Commissioner David Kessler, who already has eased the rules on pediatric drug approvals once, says more needs to be done to prod companies to develop pediatric data. The Pediatric AIDS Foundation backs legislation that would give companies an extra period of market exclusivity if they develop the needed information on the use of their pediatric drugs.

As for Samuel Fox, he has begun speaking out about kids' access to the drugs. "He wants to do something," his mother says. "He's angry right now. We're all angry."

Says Samuel: "I want to live to be an adult."

Health - pediatric labeling

August 12, 1997

PEDIATRIC DOSAGE AND LABELING ANNOUNCEMENT

DATE: August 13, 1997
LOCATION: Rose Garden
BRIEFING TIME: 1:15 pm - 1:35 pm
EVENT TIME: 1:45 pm - 2:15 pm
FROM: Bruce Reed

I. PURPOSE

To demonstrate your commitment to children's health issues by announcing a new FDA regulation to improve the safety of pediatric drugs.

II. BACKGROUND

You will be unveiling a new FDA regulation that will require drug manufacturers to study the effects of drugs on children. The regulation will apply both to certain new prescription drugs and to certain drugs currently on the market. Under this regulation, drug manufacturers will be required to complete clinical studies and place information on drug labels to help physicians make informed decisions when prescribing drugs to children.

Although children have distinct needs with regard to doses and potential side-effects of medications, most drugs have not been tested on pediatric populations. Currently, only 42 percent of drugs that have proven highly useful for children are tested on children. As a result, physicians are reluctant to prescribe many drugs to children because they do not want to risk giving an inappropriate dosage. Those physicians that do prescribe drugs without pediatric labels are forced to guess the appropriate dosage.

The FDA has identified ten drugs that are prescribed 5 million times a year to children that have not been adequately tested on children. These include Prozac, Zoloft, Ritalin, and drugs for asthma, allergies, and ear infections. In addition, less than half of the drugs used in the treatment of HIV are being studied on children. The Pediatrics AIDS Foundation has lead the fight for this new regulation on behalf of the 10,000 to 12,000 children with HIV.

Representatives from the Pediatric AIDS Foundation, the National Association of Children's Hospitals, the American Academy of Pediatrics, and other children's health organizations will be in attendance.

III. PARTICIPANTS

Briefing Participants

Secretary Shalala
Bruce Reed
Chis Jennings
Jennifer Klein
Maria Echaveste

Events Participants

Vice President
First Lady
Secretary Shalala
Regan Ralph, mother of 1 ½ year old son with asthma.

Meet and Greet Participants ^{Following} ~~(Event)~~

Bill Schmitz
Mike Friedman

Regan Ralph, mother of child with asthma, and family.
Dr. Joseph A. Zanga, Vice President, American Academy of Pediatrics
Susan DeLaurentis, Co-Founder, Pediatrics AIDS Foundation
Francesca DeLaurentis, daughter
Lawrence McAndrews, President and CEO, National Association of Children's Hospitals

IV. PRESS PLAN

Open Press.

V. SEQUENCE OF EVENTS

- You will be announced onto the stage accompanied by stage participants.
- The First Lady makes welcoming remarks and introduces Secretary Shalala.
- Secretary Shalala makes remarks and introduces the Vice President.
- The Vice President makes remarks and introduces Regan Ralph.
- Regan Ralph makes remarks and introduces you.
- You will make remarks and then depart.

VI. REMARKS

Remarks Provided by Lowell Weiss in Speechwriting.

OTC mtg

Wed

1040 - 1100

Roosevelt Rm

final rule

need to do in
with 2 years

Seniors

AARP endorsement

cosmetic industry anti

economic effect on industry is small

use of pharmacists for backdrop

See Shalala speaking
Jane Henney to introduce the VP

SHALALA

HENNEY

CONSUMER RP?

VP

room in audience for NPR

drug interaction
for seniors

~~SHALALA def press~~

~~HENNEY~~

PSA's in summer

SHALALA

HENNEY

CONSUMER

VP

program all for consumers
problem

announcement

Berkley Belsher

his graphic artist donated
time

FTC

Congressional interest no spec. in this
Commerce / Labor
just jurisdiction

HHS / FDA unites
10 each

conference call w/ health care
reporters

coll conference after the event

OEA OTC Labeling List

AMERICAN PHARMACEUTICAL ASSOCIATION

John Gans, Pharm.D

(202) 429-7567

NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

Calvin Anthony

(703) 683-8200

NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Mary Ann Wagner

(703) 549-3001

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS

Henri R. Manasse, Jr., Ph.D.

(301) 657-3000

AMERICAN MEDICAL ASSOCIATION

Margaret Garikes

(202) 789-7409

AMERICAN ACADEMY OF FAMILY PHYSICIANS

Susan Hildebrandt

(202) 232-9033

AMERICAN ACADEMY OF PEDIATRICS

Elaine Holland

(202) 347-8600

NATIONAL CONSUMERS LEAGUE

Linda Golodner

(202) 835-3323

AMERICAN ASSOCIATION OF RETIRED PERSONS

Sandra Eskin

(301) 229-5575

NATIONAL BLACK NURSES ASSOCIATION
Millicent Gorham
(301) 589-3200

PUBLIC CITIZEN HEALTH RESEARCH GROUP
Larry Sasich
(202) 588-1000

CENTER FOR MEDICAL CONSUMERS
Arthur Levin
(212) 674-7105

AMERICAN NURSES ASSOCIATION
David Hennage
(202) 651-7000 x8310

OLDER WOMEN'S LEAGUE
Deborah Briceland-Betts
(202) 783-6686

NATIONAL COUNCIL ON PATIENT INFORMATION AND
EDUCATION
W. Ray Bullman
(202) 347-6711 x14

NATIONAL COUNCIL OF PROFESSIONALS IN WOMEN'S HEALTH
Felicia Bloom, MPH
(312) 786-1468

AMERICAN MEDICAL WOMEN'S ASSOCIATION
Eileen McGrath
(703) 838-0500

NATIONAL WOMEN'S HEALTH NETWORK
Cindy Pearson
(202) 347-1140

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION
William F. Bradley
(202) 429-9260

COSMETIC TOILETRY & FRAGERANCE ASSOCIATION

Ed Cavanaugh
(202) 331-1770

FOOD MARKETING INSTITUTE

Tim Hammonds
(202) 452-8444

UNITED STATES PHARMACOEPIA

Jerome Halperin
(301) 881-0666

CONSUMERS UNION

Rhoda Karpatkin
(914) 378-2000

CONSUMER FEDERATION OF AMERICA

Mary Rouleau
(202) 387-6121

Mike Weintraub
Lash Group
(301) 230-0899

Federal Trade Commission

Lee Peeler
(202) 326-3090

Bill Schultz
Dept. of Justice
(202) 514-4015

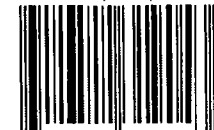
Berkey Belzar
Graphic Artist
(202) 775-0333

New Standard Labeling Format

Drug Facts							
Active ingredient (in each tablet)	Purpose						
Chlorpheniramine maleate 2 mg.....	Antihistamine						
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat							
Warnings Ask a doctor before use if you have ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives When using this product ■ drowsiness may occur ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children If pregnant or breast-feeding , ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.							
Directions <table border="1"> <tr> <td>adults and children 12 years and over</td> <td>take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours</td> </tr> <tr> <td>children 6 years to under 12 years</td> <td>take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours</td> </tr> <tr> <td>children under 6 years</td> <td>ask a doctor</td> </tr> </table>		adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours	children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours	children under 6 years	ask a doctor
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours						
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours						
children under 6 years	ask a doctor						

Drug Facts (continued)	
Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture	
Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch	

Existing Label

Allergy Tablets	
INDICATIONS: Provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies. DIRECTIONS: Adults and children 12 years and over—1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours or as directed by a physician. Children 6 to 11 years—one half the adult dose (break tablet in half) every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours. For children under 6 years, consult a physician. EACH TABLET CONTAINS: Chlorpheniramine Maleate 4 mg. May also contain (may differ from brand): D&C Yellow No. 10, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch. WARNINGS: May cause excitability especially in children. Do not take this product unless directed by a physician. If you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. May cause drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages, and do not take this product if you are taking sedatives or tranquilizers without first consulting your physician. Use caution when driving a motor vehicle or operating machinery. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately. Store at controlled room temperature 2°-30°C (36°-86°F). Use by expiration date printed on package. Protect from excessive moisture. For better identification keep tablets in carton until used.	
Made in U.S.A.  N 3 111111 11111 8	

New Standard Labeling Format

Drug Facts

Active Ingredient (in each tablet)

Chlorpheniramine maleate 2 mg.....

Purpose

Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

- glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

- drowsiness may occur ■ avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over

take 2 tablets every 4 to 6 hours;
not more than 12 tablets in 24 hours

children 6 years to under 12 years

take 1 tablet every 4 to 6 hours;
not more than 6 tablets in 24 hours

children under 6 years

ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25° C (68-77° F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch



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Title Medication use and rural seniors. Who really knows what they are taking?

Author Torrible SJ; Hogan DB

Address Health Sciences Centre, Calgary, AB.

Source Can Fam Physician, 1997 May, 43:, 893-8

Abstract

OBJECTIVE: To determine whether listings of current medications obtained from the office file of patients' attending physicians and the pharmacy record of patients' dispensing pharmacists corresponded to the actual use of medications in a group of non-institutionalized seniors residing in rural communities. **DESIGN:** In-home interviews followed by retrospective office chart and pharmacy database reviews. **SETTING:** Two rural communities in southern Alberta with populations of less than 7000 people. **PARTICIPANTS:** Twenty-five patients aged 75 years or older residing in the study communities, eight family physicians, and four dispensing pharmacies. **MAIN OUTCOME MEASURES:** Number of currently consumed prescription drugs, currently consumed over-the-counter (OTC) drugs, and stored or discontinued prescribed medications; knowledge of medications (prescribed, OTC, and stored) by family physicians and pharmacists; and number of prescribers or dispensing pharmacists. **RESULTS:** Patients took a mean of 56 prescribed medications, took a mean of 3.5 OTC medications, and had a mean of 2.0 stored or discontinued medications. Attending family physicians and primary dispensing pharmacists typically knew of only some of their patients' entire regimen of medications. **CONCLUSIONS:** Misinformation about medication consumption by seniors was common among health care providers. Undertaking routine medication reviews (with emphasis on OTC use), asking specific questions about actual consumption, encouraging use of one prescriber and one pharmacist, discouraging storage of discontinued medications and reducing use of medication samples should be of benefit.

Language of Publication
English

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Prescriptions, Drug|*; Rural Health|***MeSH Heading**Aged, 80 and over; Alberta; Drug Utilization; Female; Human;
Knowledge, Attitudes, Practice; Male; Patient Education;
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 330, and 358

[Docket Nos. 96N-0420, 92N-454A, 90P-0201, and 95N-0259]

RIN 0910-AA79

Over-The-Counter Human Drugs; Proposed Labeling Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to establish a standardized format for the labeling of over-the-counter (OTC) drug products. FDA has determined that because the design and format of labeling information varies considerably among OTC drug products, consumers often have difficulty reading and understanding the information presented on OTC drug product labeling. The proposal is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. This document supersedes the agency's proposed rule regarding the use of interchangeable terms, published in the Federal Register of March 4, 1996 (hereinafter referred to as the March 1996 proposal), and responds to the comments that were submitted to FDA as a result of that proposal (Docket No. 92N-454A). Accordingly, this document formally withdraws the March 1996 proposal. Finally, this proposal would preempt State and local rules that establish different or additional format or content requirements.

DATES: Submit written comments by June 27, 1997. Submit written comments on the information collection requirements by March 31, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Diana M. Hernandez, Center for Drug Evaluation and Research, Division of OTC Drug Products (HFD-560), Food and Drug Administration, 5600 Fishers

Lane, Rockville, MD 20857. 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Introduction

Under the Federal Food, Drug, and Cosmetic Act (the act), OTC drug products must be safe and effective in order to be marketed. The agency is conducting a comprehensive review of these drug products, which are available to consumers without a prescription. As a result of this review, the agency has required specific language to be included in the labeling of many OTC drug products, describing the uses, directions, warnings, drug interaction precautions, active ingredients, and other information, so that consumers can use these products safely and effectively.

As a result of escalating health care costs and the increasing availability of OTC drug products, some of which were once available only by prescription, more consumers are engaging in self-medication. Thus, it is increasingly important that consumers read and understand the information on drug product labeling.

On January 6, 1993, the agency issued final regulations to help consumers read and understand the information on food product labeling (58 FR 2079). The new regulations, which provide for a standardized graphic presentation for food nutrients, were issued in response to the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535, November 8, 1990). The 1990 amendments directed the Secretary of Health and Human Services to issue implementing regulations to:

- require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet.

(Section 2(b)(1)(A) of the 1990 amendments) This new, standardized format allows the consumer to judge the significance of the level of a particular nutrient in a particular food in the context of the total daily diet.

FDA believes it is equally important for consumers to be able to make reasoned decisions about the drugs they take. On August 24, 1995 (60 FR 44182), FDA proposed a comprehensive program to increase the distribution and quality of easy to read and easy to understand written information about prescription drugs to patients. Recently enacted legislation provides that various private entities will work to transform these goals into a satisfactory program.

FDA is now proposing to improve the

way that information on the labeling of OTC drug products is communicated.

The design, format, and placement of required labeling information varies considerably among OTC drug products. As a result, consumers often have difficulty finding, reading, and understanding this labeling information. Modifying and simplifying the manner in which the information is presented can improve the legibility and understandability of OTC drug product labeling. FDA is, therefore, proposing to establish a standardized format for the labeling of all marketed OTC drug products. This action is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products.

The agency is proposing five types of labeling changes for OTC drug products. First, the proposal would require that OTC drug product labeling include standardized headings and subheadings presented in a standardized order, as well as standardized graphical features, such as the Helvetica type style, minimum standards for type size, leading (i.e., space between two lines of text), kerning (spacing between letters), upper and lower case letters, and graphical highlights.

Second, the proposal would permit manufacturers, packers, or distributors to delete specific terms, referred to for purposes of this rulemaking as "connecting terms," that are currently required in OTC drug product labeling.

Holders of approved new drug applications (NDA's), antibiotic drug applications, and abbreviated new drug and antibiotic drug applications (referred to collectively in this document as "marketing applications") who wish to delete a "connecting term" in their labeling would also be permitted to delete the "connecting term" in accordance with 21 CFR 314.70. Typically, such terms are found within quotation marks in OTC drug monographs and in specific regulations. Deletion of these terms would only be permitted where deletion would not change the meaning of the information. Deletion of these terms would not be required but, rather, would be permitted as needed to simplify the presentation of labeling information (which is usually presented in a lengthy paragraph format), so that manufacturers, packers, distributors, or applicants can comply with the proposed, easier to read format.

Third, the proposal would expand the list of "interchangeable terms" found in the current regulations (§ 330.1(i) (21 CFR 330.1(i))), to facilitate the use of more concise, easier to understand

Background

Nutrition Labeling

simple, easy to read

(eg. "Consult a doctor", "Due to", "While taking this product")

for older people; warnings easier to read. combination; cough/cold

statements on the labeling of OTC drug products. Expanding the list of interchangeable terms would provide manufacturers, packers, distributors, or applicants with a broader choice of terms for a particular statement on the labeling. This proposed rule addresses the same interchangeable terms (as well as additional interchangeable terms) that were proposed on March 4, 1996 (61 FR 8450). Thus, this proposal formally withdraws the March 1996 proposal.

Fourth, the proposal would amend specific warning language required under current monographs and regulations (the pregnancy-nursing warning, the "keep out of reach of children" warning, ~~and the overdose/accidental ingestion warning~~ (§§ 201.63, 201.314(a) and (g)(1) (21 CFR 201.63, 201.314(a) and (g)(1)), and 330.1(c)) to make the warnings easier to understand and more concise.

Finally, in order to ensure that OTC drug product labeling is easier to read and understand, and to ensure the safe and effective use of OTC drug products, FDA is proposing to preempt State and local rules that establish different or additional format or content requirements than those in this proposed rule. The agency believes that such State and local requirements for OTC drug labeling would undermine the agency's objectives of ensuring the safe and effective use of OTC drug products through the use of a uniform easy-to-read format for all OTC drug product labeling.

II. Regulatory Scheme for OTC Drug Product Labeling

A. Current Statutory and Regulatory Requirements

The act and FDA's implementing regulations require specific information on the labeling of all OTC drug products. FDA regulations, including OTC drug monograph regulations, require information on the labeling of OTC drug products by product type (e.g., antacid, bronchodilator). Additionally, manufacturers, distributors, and packers may place the information required under OTC drug monographs in any format and order, as long as the information complies with the appropriate monograph and other applicable regulations. OTC drug products marketed under a marketing application must be labeled in accordance with the labeling approved in the application. As a result, the format of required labeling information varies considerably among OTC drug products.

Under section 502 of the act (21 U.S.C. 352), a drug is misbranded if the labeling does not contain: The name and place of business of the manufacturer, packer, or distributor and a statement of the quantity of contents in terms of weight, measure, or numerical count (section 502(b)); the established name, if any, of the drug, and the established name of each active ingredient if the drug is fabricated from two or more ingredients (section 502(e)); and adequate directions for use and adequate warnings against unsafe use (section 502(f)). In addition, a drug is misbranded if its labeling is false or misleading in any particular (section 502(a)), or if it is dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling (section 502(j)).

The act also addresses the prominence and conspicuousness of drug product labeling. Section 502 of the act states that:

A drug * * * shall be deemed to be misbranded—

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

FDA has implemented the general labeling requirements under section 502 of the act in part 201 of the regulations (21 CFR part 201). Section 201.1 sets forth requirements with respect to the name and place of business of the manufacturer, packer, or distributor. Section 201.5 defines adequate directions for use as "directions under which the layman can use a drug safely and for the purposes for which it is intended." Adequate directions include a statement of all the manufacturer's intended uses of the drug (frequently termed "Indications"), quantity of dose, route or method of administration, and the frequency, duration, and timing of administration (§ 201.5). Section 201.10 sets forth requirements for ingredient information required by section 502(e) of the act.

Section 201.17 sets forth requirements concerning the location of expiration dating, which is required under the current good manufacturing practice (CGMP) regulations (§ 211.137 (21 CFR 211.137)). Section 201.18 requires a lot number "capable of yielding the complete manufacturing history of the package." A related CGMP regulation (§ 211.132 (21 CFR 211.132)) that

applies to most OTC drug products requires a labeling statement alerting consumers to certain tamper-resistant packaging features (§ 211.132(c)).

Sections 201.60 through 201.62 define and set forth requirements for the principal display panel of OTC drug product labeling. The principal display panel is defined as the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. The information required to be on the principal display panel includes a statement of identity of the drug and the net quantity of contents of a drug. The statement of identity must include the established name of the drug, as well as the pharmacological category or principal intended action of the drug. If the drug is a mixture and has no established name, its general pharmacological actions or its principal intended actions must be stated (§ 201.61(b)). Under § 330.1(c)(1) (21 CFR 330.1(c)(1)), the statement of identity of a drug covered by an OTC drug monograph shall be the term or phrase used in the applicable monograph.

Under section 502(e)(3) of the act, the established name of a drug is generally derived from its official title in an official compendium. When the established name for a single or a multiple ingredient drug product is stated in terms of the active ingredient(s), the active ingredient(s) will appear on the principal display panel. However, when a multiple ingredient product does not have an established name, the active ingredients are not required to be placed on the principal display panel (§ 201.61(b)), but may be prominently placed on the back or side panel in accordance with section 502(e) of the act and §§ 201.10 and 201.15. Under § 330.1(j), the agency recommends that the labeling of a product contain the quantitative amount of each active ingredient, expressed in terms of the dosage unit stated in the directions for use (e.g., tablet, teaspoonful).

Current regulations also address the format of OTC drug product labeling, but do not require a specific print size or print style. For example, implementing regulations in § 201.15 describe a number of situations in which the agency considers information on a drug product's label as lacking the prominence and conspicuousness required by section 502(c) of the act. For example, a statement may lack the prominence and conspicuousness required by section 502(c) of the act by reason of, among others, "[s]mallness or style of type in which such word,

Coverage of rule: drugs & drug cosmetics

IX. References

The following references are on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Miller, G. A., "The Magical Number Seven, Plus or Minus Two: Some limits on Our Capacity for Processing Information," *Psychological Review*, 101(2):343-352, 1994.

2. Shiffrin, R. M., and R. M. Nosofsky, "Seven Plus or Minus Two: A Commentary On Capacity Limitations," *Psychological Review*, 101(2):357-361, 1994.

3. Allen, P. A., and L. C. Crozier, "Age and Ideal Chunk Size," *Journal of Gerontology: Psychological Sciences*, 47(1):47-51, 1992.

4. Wood, R., and A. Bandura, "Impact of Conceptions of Ability on Self-Regulatory Mechanisms and Complex Decision Making," *Journal of Personality and Social Psychology*, 56(3): 407-415, 1989.

5. Chandler, P., and J. Sweller, "Cognitive Load Theory and the Format of Instruction," *Cognition and Instruction*, 8(4):293-332, 1991.

6. Food and Drug Administration, "National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs," April, 1998, Docket No. 98D-0149, Dockets Management Branch.

~~7~~ Comment No. 718, Docket No. 96P-0318, Dockets Management Branch.

~~8~~ Comment No. 684, Docket No. 96P-0318, Dockets Management Branch.

9. *Webster's Ninth New Collegiate Dictionary*, p. 371, 1990.

10. Nonprescription Drug Manufacturers Association, "Label Readability Guidelines," May 1996, in OTC vol. 28FR, Docket No. 96N-0420, Dockets Management Branch.

11. Watanabe, R. K., "The Ability of the Geriatric Population to Read Labels on Over-the-Counter Medication Containers," *Journal of the American Optometric Association*, 65:32-37, 1994.

~~12~~ Comment No. CP1, Docket No. 96P-0318, Dockets Management Branch.

13. Letter from R. G. Chesemore, FDA, to B. Nakutin, dated April 22, 1997, coded PDN1, Docket No. 96P-0318, Dockets Management Branch.

Devorah - I believe they cited more in the proposed rule.
I'll check with FDA Monday



**Executive Office of the President of the United States
Office of Management and Budget**

*Office of Information and Regulatory Affairs
Human Resources and Housing Branch
New Executive Office Building
Room 10235
Washington, DC 20503*

FAX TRANSMITTAL

FAX: 202-395-6974

DATE: 3/3

TO: Chris/Deborah

FROM: Wendy Taylor

Total number of pages (Including Transmittal Sheet): _____

Recipient's Fax Number: _____

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Comments:

Here's the list of contacts that I pulled from
the comments on the OTC rule. Most should be at least
generally supportive of the rule (with the exception of
the cosmetic groups - depending on how the rule turns out).
If you want to see the individual comments of any on
this list, just let me know.

Thanks for your help!

OTC Drug Companies

Nonprescription Drug

Manufacturers Association (NDMA)	James D. Cope (Pres.)	(202) 429-9260
Warner Lambert	Hans F. Knapp	(201) 540-2000
Bausch & Lomb	Kim S. DeVitto	(716) 338-6000
Procter & Gamble*	Christine H. Moorman	(Mason, OH)
Novartis	Vincent De Stefano	(908) 598-7706
Schering-Plough	Ronald J. Garutti (VP)	(908) 604-1640
Merck	Edwin L. Hemwall (VP)	(West Point, PA)
Private Label Manufacturers Assn.	Brian Sharoff (Pres)	(212) 972-3131
Pfizer	Stephen Cristo	(212) 573-7827
Bayer	John Tomaszewski	(201) 254-5000

* P&G also raised serious concerns with the cosmetic requirements

Cosmetics

Cosmetic, Toiletry, and Fragrance Assn.	Thomas J. Donegan (VP)	(202) 331-1770
Helene Curtis	Bruce V. Varner	(312) 661-0222
Estee Lauder (represented by Arent Fox)		

General

American Medical Association	P. John Seward	(312) 464-5000
American Dental Association	Gary Rainwater (Pres)	(312) 440-2871
Association of Food and Drug Officials	Dan S. Smyly (Pres)	(717) 757-2888

Consumer

National Consumers League	Linda Golodner (Pres)	(202) 835-3323
National Women's Health Resource Center	Amy Niles	(202) 293-6045
Consumer Helath Information Corp.	Dorothy L. Smith (Pres)	(703) 734-0650

Kids

American Academy of Pediatrics	Robert E. Hannemann (Pres)	(202) 347-8600
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Elderly

AARP	Martin A. Corry	(202) 434-2277
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Pharmacists

American Pharmaceutical Assn.	John A. Gans (Exec. VP)	(202) 628-4410
National Community Pharmacists Assn.	Calvin Anthony (Exec. VP)	(703) 683-8200
National Assn. of Chain Drug Stores	S. Lawrence Kocot	(703) 549-3001

**PRESIDENT CLINTON ANNOUNCES NEW MEASURES TO INCREASE
AVAILABILITY OF INFORMATION ON SAFE USE OF MEDICATIONS USED
TO TREAT CHILDREN**

August 13, 1997

Today, President Clinton unveiled a new FDA regulation that will protect children by requiring manufacturers to study the safety and appropriate dosage levels of drugs for pediatric populations. The regulation also requires proper labeling of drugs for use in children. Even though many drugs affect children differently than adults, most drugs have not been tested on pediatric populations. Under this rule, manufacturers of prescription drugs likely to be used by children will be required to complete studies and place information on drug labels to help pediatricians and other health care providers make scientifically-based treatment decisions when prescribing drugs to children.

WHY THIS REGULATION IS NEEDED

Most drugs -- even those commonly used in children -- have not been widely tested on pediatric populations. According to the American Academy of Pediatrics, only a small fraction of drugs and biological products marketed in the United States have had clinical trials performed in pediatric patients. Despite evidence that drugs affect children differently than adults, 80 percent of all drugs marketed in the United States have been labeled for use by infants, children, and adolescents. Forty-two percent of drugs that are widely used in pediatric populations have been tested on children.

- Many drugs commonly given to children under the age of six including Prozac, Zoloft, Ritalin, and drugs for asthma, allergic reactions, and ear infections are inadequately tested and labeled for use in children. These drugs, taken together, are given to over five million children each year.
- Less than half of the drugs used in the treatment of HIV infections carry any safety or effectiveness information for children. Of those that do, the data is often incomplete.
- Safety and effectiveness information is especially sparse for the over seven million children under the age of two.
- The percentage of drugs being tested on children decreased by over one-third between 1996 and 1991.

Drugs are likely to have a different impact on children than on adults. The appropriate use and dosage levels of medication for children and adults is usually different because of disparities in organs, the immune system, and metabolism.

Children who take prescription drugs that have not been tested on pediatric populations are at serious risk for unexpected adverse reactions. Evidence suggests that prescribing drugs that have not been adequately tested on children can be extremely dangerous. One example of the possible harm is the case of "gray baby syndrome" where a number of babies died from chloramphenicol, an antibiotic that their immature livers were unable to accept. Other children had withdrawal symptoms from prolonged administration of fentanyl, a pain killer used as an adjunct to anesthesia in infants and small children. Still others have suffered seizures and cardiac arrest from bupivacaine, a local anaesthetic not adequately tested in pediatric populations.

Some physicians are reluctant to prescribe much needed therapies to children because they have not been tested on pediatric populations. Physicians report that they have denied children important new drugs because, in the absence of adequate testing and labeling, they would have to guess at an appropriate dosage, and they do not want to take that risk. As a result, too many children do not receive the treatment they need and deserve.

SUMMARY OF THE RULE

Pediatric Studies for New Drugs. Under this proposed rule, manufacturers of new drugs would have to do studies on pediatric populations under two circumstances: when the product represents a meaningful therapeutic benefit over existing treatments; or when the product is expected to be widely used on pediatric patients. The FDA anticipates that about twelve new drugs each year would meet this requirement. Manufacturers could receive waivers from the requirement to do a pediatric study under any one of the following circumstances:

- (1) The product does not represent meaningful benefits over existing treatments and is not likely to be used on a substantial number of pediatric patients as a whole; or
- (2) Necessary studies are impossible or highly impractical-- i.e., the number of patients is too small or geographically diverse; or
- (3) There is evidence strongly suggesting that the product would be unsafe or ineffective in pediatric populations.

Pediatric Studies For Existing Drugs. For drugs that are already on the market, the new FDA regulation requires additional testing on the pediatric population only if there is a "compelling need for more information." The criteria used is:

- (1) If the product is widely used in pediatric populations and the absence of adequate labeling could pose significant risks to pediatric populations; or
- (2) If the product is indicated for very significant or life threatening illness, but additional dosing or safety information is needed to permit its safe and effective use in pediatric patients.

President Clinton Continues to Fight to Improve the Health of Our Nation's Children

- **Children and Prescription Drug Testing.** Today's announcement requiring manufacturers to do studies on pediatric populations for new prescription drugs and those currently on the market builds on an impressive array of children's initiatives advocated by President Clinton.
- **Children and Insurance Coverage.** The President fought hard to ensure that the Balanced Budget Act included \$24 billion -- the largest investment in children's health care since the passage of Medicaid in 1965 -- to provide meaningful health care coverage to as many as five million of our nation's uninsured children. He also fought to include revenue from a 20 cent tobacco tax which will not only further reduce the number of uninsured children, but it will also serve as a financial barrier to help prevent our children from starting to smoke in the first place.
- **Children and Tobacco.** The President issued guidelines to eliminate easy access to tobacco products and to prohibit companies from advertising tobacco to kids. Each day about three thousand children become regular smokers and 1,000 of them will die from a tobacco-related illness. According to former FDA Commissioner David Kessler, the possibility of a comprehensive, public health oriented settlement with the tobacco industry could not have come about without the President's leadership in this area.
- **Children and Insurance Reform.** By signing the Kassebaum-Kennedy bill into law last year, the President helped millions of American children keep their health care coverage when their parents lose or change jobs.
- **Children and Juvenile Diabetes.** The President fought to include \$150 million (\$30 million annually for five years) for research to help find the cure for diabetes. Americans with this disease often suffer severe consequences, such as blindness and kidney disease, even when they receive the best treatment and care. The HHS Secretary will have discretion to target the new funds toward the best scientific opportunities. This represents the largest single new investment in Juvenile Diabetes.
- **Children and Immunization.** As the President recently announced, over 90 percent of America's toddlers in 1996 received the most critical doses of each of the routinely recommended vaccines -- surpassing the goal set by the President in 1993.
- **Children and the Environment.** Earlier this year, the President signed an Executive Order to reduce environmental health and safety risks to children by requiring agencies to strengthen policies and improve research to protect children and ensure that new regulations consider special risks to children.
- **Children and Medicaid.** Throughout his Administration, the President has fought to preserve and strengthen the Medicaid program; its coverage of about 20 million children, makes it the largest single insurer of children. The Administration has partnered with states through Medicaid waivers to expand coverage to hundreds of thousands of children.

PROPOSED

**OVER-THE-COUNTER
DRUG LABELING
CAMPAIGN**

OTC CAMPAIGN

background
objectives

messages

products

dissemination

partnerships

MESSAGES

easier to read and understand
speak with health care providers

AUDIENCE

general public
elderly
childcare providers
health professionals
national organizations
media



PRODUCTS (phases I,II)

theme and graphic identity

3 print public service announcements (PSA)

2 radio PSAs

5 live-read radio announcements

consumer brochure/partnership piece

camera-ready newspaper article

press release/backgrounder

radio actuality

BUDGET

FY97: 150K (contract)

FY98: ??

WISH LIST *If had more funding.*

Spanish language materials
outreach to more magazines
in-store posters - NDMA?
kick-off media event
audio news release
satellite media tour
exhibit panels
increase printing budget

DISTRIBUTION

media outlets

magazines

newspapers

radio stations

health, drug and trade press

direct mail

Internet

conferences

Consumer Information Center, Pueblo

FDA (OHA, OCA, OPA, CDER)

field offices

pharmacies

- NDMA } printing & distribution

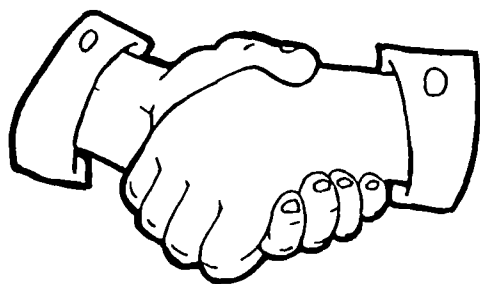
FDA publications

FDA Consumer

Medical Bulletin

other federal agencies

national associations



PARTNERSHIPS

benefits of partners

larger audiences

printing costs

distribution channels

POTENTIAL PARTNERS:

American Academy of Family Physicians
American Academy of Pediatrics
American Academy of Physician Assistants
American Association of Health Education
American Association of Retired Persons
American Medical Women's Association
American Pharmaceutical Association
Chain Drug Marketing Association
Consumer Federation of America
Food Marketing Institute
National Association of Chain Drug Stores
National Association of Child Care Providers
National Association of Poison Control
National Consumers League
National Council on Patient Information and Education
National Institutes of Health
* Nonprescription Drug Manufacturers Association
Society for Public Health Education

AMIA NMA
Retired Drug

Proposed Magazines for FDA Print PSA Distribution List

General Fitness & Personal Health:

Arthritis Today
Better Health Magazine
Consumer Reports on Health
Country Living's Healthy Living
Fit Magazine
Fitness
Fitness Plus
Harvard Health Letter
Health
Health & Fitness
Health & You
Heart & Soul
Let's Live
Living Fit
Mayo Clinic Health Letter
Medical Update
Prevention
Prime Health & Fitness
Remedy
Self
Shape

Parenting & Family:

American Baby
Baby
Baby Magazine
Baby Talk
Child
City Family
Family
Family Circle
Family Fun
Family Life
Family, Safety, and Health
Fit Pregnancy
Great Expectations
Healthy Kids

Parenting Group
Parenting Magazine
Parents
Parents Digest
Parents Expecting
Sesame Street Parents
Working Mother

Women's General Interest:

Allure
American Health for Women
American Woman
Better Homes & Gardens
Cosmopolitan
Essence Magazine
First for Women
Good Housekeeping
Jane
Ladies' Home Journal
Mademoiselle
McCall's
More
New Woman
Redbook
Vanity Fair
Vogue
Woman's Day
Woman's World
Women's Fitness
Women's Health Monitor

Men's General Interest:

Details
Esquire
GQ
Maxim
Men's Fitness
Men's Health

Men's Journal

Mature Lifestyle/Older Adults:

AARP Bulletin
Answers: The Magazine For Adult
Children of Aging Parents
Fifty Plus
Health, Money & Travel
Mature Lifestyles
Mature Outlook
McCall's Extra Edition
Modern Maturity
New Choices for Living Even Better
After 50
Senior Highlights
Senior Magazine
Today's Seniors
Vantage

Minority:

Black Enterprise
Ebony
Ebony Man
Emerge
Hispanic
Jet
Latina Magazine
Moderna
Ser Padres Magazine

General:

Consumers Digest
Consumer Reports
Life Magazine
Newsweek
People
Reader's Digest
Saturday Evening Post
Time
TV Guide
U.S. News & World Report
USA Today Magazine

EVALUATION

print and broadcast usage
partnerships outreach

COORDINATING EFFORTS

CDER

Division of OTC Products

DDMAC

FDA OC

FDA OEA:

OPA

OCA

OWH

OHA

OSHI

ORA

General Counsel, Ethics

Other Federal agencies

National Organizations

P.51 Insert II

When developing drug labeling, the agency considers the risks and benefits of a drug, the intended use, and the need to communicate limitations or restrictions about use to the target population. The quantity and complexity of information which must be communicated to ensure appropriate product selection, convey the effectiveness of the drug, communicate risks, and provide complete directions for use, varies with the drug ingredient, the target population, the disease or symptoms the product is intended to treat or prevent, and with related information about the condition^S which must be provided for the safe and effective use of the drug.

In some cases (e.g., lipsticks or lip balms), minimal information is needed for the safe and effective use of the product. Such products may^{typically} be packaged in small amounts, have a very high therapeutic index, carry extremely low risk in actual consumer use situations, provide a favorable public health benefit, require no specified dosage limitation, and require few^{specific} warnings and no general warnings (e.g., pregnancy or overdose warnings). Products that meet these characteristics will be identified, addressed, and specifically considered for exemptions in their respective monograph^S and drug marketing application.¹



**American
Pharmaceutical
Association**

2215 Constitution Avenue, NW
Washington, DC 20037-2985
(202) 628-4410 Fax (202) 783-2351
<http://www.aphanet.org>

*The National Professional
Society of Pharmacists*

March 10, 1999

The Honorable Albert Gore Jr.
Vice President of the United States
Office of the Vice President
Old Executive Office Building
Washington DC 20501

Dear Mr. Vice President,

The American Pharmaceutical Association (APhA), the national professional society of pharmacists, applauds the efforts of the Food and Drug Administration to improve the labeling on over-the-counter medications. With more than 53,000 members including pharmacists, pharmacy students, and pharmaceutical scientists, APhA believes that presentation of vital information in a standardized format will help consumers better understand how to use their medications.

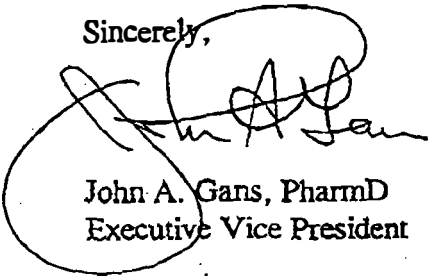
It is important that consumers have access to consistent, comprehensive and comprehensible information on OTC drug products they are either using or evaluating for potential purchase and use. The new labeling requirements will help achieve this goal.

When used appropriately, these products are essential tools for self-care, but inappropriate use as a result of insufficient information is an untenable situation. FDA's efforts will certainly improve this situation, and the nation's pharmacists look forward to providing additional assistance to help patients make the best use of their medications.

Importantly, the new labeling should direct consumers to consult with pharmacists or other health care professionals with any questions. Over-the-counter medications are safe when used appropriately—and the combination of the new labeling and follow-up collaboration with a pharmacist or other health care professional—will support appropriate use.

Again, APhA applauds the FDA for their efforts to improve labeling of over-the-counter medications.

Sincerely,



John A. Gans, PharmD
Executive Vice President



Better Health
Through Responsible
Self-Medication

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

March 11, 1999

The Vice President
The White House

Dear Mr. Vice President:

The Nonprescription Drug Manufacturers Association* is pleased to see the finalization of the regulation on the Information Panel of over-the-counter (OTC) drug products. We expect this new rule to help consumers read OTC labels even more easily.

The modern era of label readability began in 1990, when the State of California initiated work with our industry to improve the readability of our products' labeling. In the process, we adopted a voluntary program on label readability that resulted in changes to tens of thousands of linear miles of labeling. We have had many meetings with FDA, consumer groups, and outside readability experts over several years, to encourage the development of this regulation on label content and format as the next logical step.

Our dedicated efforts on label readability were officially recognized in commendations by the California state legislature in 1994, and then by FDA's Center for Drug Evaluation and Research in 1996.

As a result, many features of the FDA rule are very similar to our recommendations. The new regulation will allow the use of simpler, more easily understood terms in labeling. Standard headings and a standard order will make the information easier to find on the labels. The bulleted format will help consumers organize label elements into easy-to-read blocks, rather than long paragraphs. The warning section is logically organized. And good use of white space will be easier on the eyes.

This is an example of how a government/industry partnership can work for the benefit of consumers, and how FDA can make use of the expertise of the industry. We extend our special thanks to FDA and our cadre of labeling experts in our member companies, and we look forward to the next step in making the labeling of OTC drug products even easier to read.

Sincerely,

A handwritten signature in dark ink, appearing to read 'James D. Cope', is written over a horizontal line.

James D. Cope
President

/b

NACDS

National Association of Chain Drug Stores

March 10, 1999

The Honorable Albert E. Gore, Jr.
Vice President of the United States
Old Executive Office Building
Washington, DC 20501

Dear Mr. Vice President:

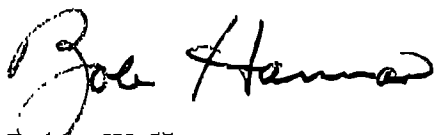
NACDS commends the Food and Drug Administration (FDA) for its initiative to make the labels of over-the-counter drug products more consumer friendly. We are especially pleased that the new labels will include the term "Ask your doctor or pharmacist".

The National Association of Chain Drug Stores (NACDS) membership consists of over 130 chain community pharmacy companies, operating more than 31,000 retail community pharmacies with annual sales totaling over \$135 billion, including prescription and over-the-counter (OTC) medications.

We believe that recommending that consumers talk with their pharmacist about OTC medications is good health care. Encouraging pharmacist interaction with consumers on OTC products is also consistent with recent attempts by consumer groups and the pharmacy community to increase the quality and quantity of useful information being provided to consumers with their prescription medications.

We appreciate FDA's and the Administration's recognition of the valuable contributions the pharmacist makes to the health and well being of American consumers.

Sincerely,



Robert W. Hannan
Interim President and
Chief Executive Officer

cc: Thomas J. McGinnis
Deputy Commissioner for Health Affairs, FDA

**DIVISION OF DRUG MARKETING, ADVERTISING AND COMMUNICATION
CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION
FAX TRANSMITTAL**

DATE: March 10, 1999
TO: Devora Adler
PHONE: 202-456-5707
FAX: 202-456-5557
FROM: KATHRYN J. AIKIN, PH.D.
5600 FISHERS LANE ROCKVILLE, MD 20857
ROOM: 17B04 MAIL CODE: HFD-40
PHONE: 301-827-2828 FAX: 301-594-6759
SECRETARY: LAURA RIDDLE

REMARKS:

Devora,
Enclosed is a brief summary of Studies A & B. These
studies are part of the OTC Labeling Rule. Please feel
free to contact me if you require further information.
-Kit Aikin

NUMBER OF PAGES INCLUDING COVER SHEET: 5

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND MAY BE PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. IF YOU ARE NOT THE ADDRESSEE, OR A PERSON AUTHORIZED TO DELIVER THE DOCUMENT TO THE ADDRESSEE, YOU ARE HEREBY NOTIFIED THAT ANY REVIEW, DISCLOSURE, DISSEMINATION, COPYING, OR OTHER ACTION BASED ON THE CONTENT OF THIS COMMUNICATION IS NOT AUTHORIZED. IF YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY TELEPHONE AND RETURN IT TO US BY MAIL TO 5600 FISHERS LANE ROCKVILLE, MD 20857, HFD-40, 17B17. THANK YOU.

7

probability that the information graphically identified as important is subject to more complete processing, leading to increased communication of this information.

The agency believes that the two studies it conducted helped to confirm that the new labeling format will significantly increase communication of OTC drug product information to consumers.

START

A. Study A

Study A was designed to compare the proposed labeling format with a prototype of the existing format, and to test the use of highlighting on the communication of important labeling information, including directions for use and warnings.

The agency tested four variables: (1) Label format (old format vs. proposed format), (2) drug type (cough-cold vs. pain reliever), (3) the use of highlighting, and (4) consumer attention (divided vs. focused)^{1/}. Highlighting, label format, and drug type were varied in the design of the sample product label, and attention was varied through instructions given to the respondent. The study included 1,202 respondents in 8 geographically distributed shopping malls in the United States, with approximately equal numbers of respondents from each location. Respondents were asked to evaluate various presentations of label information on several OTC drug package samples and were asked questions about each label to determine their knowledge, opinions, and willingness to read the label.

1/ Study participants read a food label, then a drug label. About half of the people were told they would be asked questions about both labels (divided attention); other half were told they would be tested only on the drug label (focused attention).

The study demonstrated that the proposed new format took less time and was easier to read and understand than the current format. The new format helped respondents make more correct product use decisions that required a simple search for information in the labeling. Study respondents indicated a general preference for the proposed format and, when their attention was divided, respondents felt more confident in their ability to use the new format. In addition, the study demonstrated that when presented with labeling containing more highlighted elements, respondents preferred such labeling and rated it as easier to read and understand. Under conditions with more highlighting, respondents who were instructed to focus on the labeling made more correct product use decisions when these decisions required mental application of labeling information, compared to respondents whose attention was divided. When the labeling contained less highlighting, there was no difference in the number of correct product use decisions between respondents who had focused or divided attention.

The results from Study A suggest that consumers relying on OTC drug product information utilizing the new labeling format will be (1) more confident in their ability to use the information in the labeling and (2) better able to make correct product use decisions.

B. Study B

Study B was designed to examine preferences for OTC drug product labeling formats by incorporating several design variations. Four variables were tested: (1) The order of the "Warning(s)" and "Direction(s)" section in the label (i.e., warnings before directions vs. warnings after directions), (2) the placement of the "Active ingredients" section at the top of the label vs. bottom of the label, (3) the use of a title as an introduction to the required labeling information ("Medication Facts" vs. no title), and (4) the use of dividing lines between sections (thick vs. thin lines).

This study included 904 respondents in 8 geographically distributed shopping malls in the U.S., with approximately equal numbers of respondents from each location. The respondents were asked to evaluate 16 label variations of either a sample cough-cold or sunscreen drug product. The respondents were also asked to rank the randomly ordered labels from most to least preferred, to specify the reason(s) for their first and second choices, and to rate a current OTC drug product label that ^{was} ~~is~~ not in the new labeling format. ✓

Overall, this study demonstrated that respondents preferred a title as an introduction and visual cue to the required labeling information. Labels with the title were viewed as more credible and readable than labels with no title. When asked why they preferred the label ranked as number one, the respondents indicated that they liked the layout because it: (1) Was easy

10

to read (16.7 percent), (2) begins with "Medication Facts" (14.6 percent), and (3) has "Medication Facts in bold/large print" and "Warnings" first/at top/under "Medication Facts" (17 percent). When the impact of all four design variables was analyzed simultaneously, the introductory title had the greatest relative impact on preference rankings.

With respect to the other variables the agency tested in Study B, preferences were much less impressive. These findings are addressed in other parts of this document that discuss each of these subjects. (See sections IV.A., IV.C., and IV.D. of this document.)

IV. The Agency's Conclusions on the Comments

Stop

A. Scope--§ 201.66(a)

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of OTC drug products marketed pursuant to a final OTC drug monograph, an approved new drug (NDA) or abbreviated new drug (ANDA) application under section 505 (21 U.S.C. 355) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331(1)), and products marketed where there is no final OTC drug monograph or application and the product is not subject to an ongoing OTC drug review rulemaking.

1. Several comments asked that § 201.66 not apply to homeopathic drug products, including those products listed in the Homeopathic Pharmacopeia of the United States as well as those not so listed. One comment, however, recommended that the

BEFORE

Allergy Tablets

INDICATIONS: Provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies.

DIRECTIONS: Adults and children 12 years and over—1 tablet every 4 to 6 hours, not to exceed 6 tablets in 24 hours or as directed by a physician. Children 6 to 11 years—one half the adult dose (break tablet in half) every 4 to 6 hours, not to exceed 3 whole tablets in 24 hours. For children under 6 years, consult a physician.

EACH TABLET CONTAINS: Chlorpheniramine Maleate 4 mg. May also contain (may differ from brand): D&C Yellow No. 10, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch.

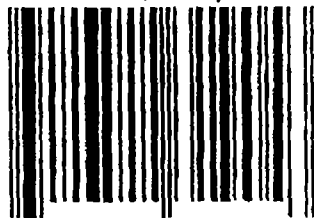
WARNINGS: May cause excitability especially in children. Do not take this product unless directed by a physician, if you have a breathing problem such as emphysema or chronic bronchitis, or if you have glaucoma or difficulty in urination due to enlargement of the prostate gland. May cause drowsiness; alcohol, sedatives and tranquilizers may increase the drowsiness effect. Avoid alcoholic beverages, and do not take this product if you are taking sedatives or tranquilizers without first consulting your physician. Use caution when driving a motor vehicle or operating machinery. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.

Store at controlled room temperature 2°-30°C (36°-86°F).

Use by expiration date printed on package.

Protect from excessive moisture.

For better identification keep tablets in carton until used.



N
3 1 1 1 1 1 1 1 1 1 1 1 8

Made in U.S.A.

AFTER

Allergy Tablets

Drug Facts

Active Ingredient (in each tablet)

Chlorpheniramine maleate 2 mg.....Antihistamine

Purpose

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat

Warnings

Ask a doctor before use if you have

- glaucoma ■ a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this product

- drowsiness may occur ■ avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)

Other information ■ store at 20-25°C (68-77°F) ■ protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch



Founded 1881

Better Health
Through Responsible
Self-Medication

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

October 6, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., rm. 1-23
Rockville, MD 20857

**COMMENTS OF
THE NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION
ON PROPOSED LABELING REQUIREMENTS FOR
OVER-THE-COUNTER HUMAN DRUGS**

62 Fed. Reg. 9024 (February 27, 1997)

Docket Nos. 96N-0420, 92N-454A, 90P-0201, and 95N-0259

2128
7 OCT -6 P4:32

The Nonprescription Drug Manufacturers Association (NDMA) submits these comments in response to FDA's notice of proposed rulemaking to establish a standardized format for the labeling of nonprescription or over-the-counter (OTC) drug products.¹ NDMA is the national trade association representing manufacturers and distributors of nonprescription medicines. NDMA members account for more than 95 percent of OTC drug sales in the United States.

NDMA wholeheartedly endorses the goal of making OTC drug labeling more user-friendly, and we commend FDA for the excellent work reflected in its proposal. As FDA has recognized,² NDMA has long been actively engaged in efforts to improve labeling

¹62 Fed. Reg. 9024 (February 27, 1997).

²See 62 Fed. Reg. at 9031.

96N-0420

C 716

through such initiatives as the 1991 *Label Readability Guidelines*. In response to FDA's solicitation of comments and public hearing announcement in 1995,³ NDMA developed and proposed a standardized labeling format and simplified labeling language. We presented this proposal at the public hearing on September 29, 1995, and in post-hearing comments submitted on November 14, 1995, which are part of the rulemaking record and for the most part will not be repeated here.

FDA's notice of proposed rulemaking published on February 27, 1997, represents the most far-reaching effort that the agency has ever undertaken to improve OTC drug labeling. NDMA strongly supports this effort and the large majority of the elements of FDA's proposal. We have recommendations, however, to improve the workability and usefulness of the regulation through provisions for additional flexibility regarding typography and certain changes in warning format and content. We also recommend an exemption for small packages.

These comments are organized as follows. Following an executive summary, part I provides introductory comments. Part II addresses labeling content and format, including issues relating to type size and style. Part III supports and amplifies on FDA's proposal for national uniformity (preemption). Part IV addresses two implementation issues, namely cost and the effective date of the regulation. Finally, Part V provides summary responses to FDA's specific requests for comments. Appendices A-H appear after Part V.

³60 Fed. Reg. 42578 (August 16, 1995).



Bringing lifetimes of experience and leadership to serve all generations.

November 7, 1997

Michael Friedman, M.D.
Lead Deputy Commissioner
The Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Docket No. 96N-0420, 92N454A, 90P-0201, and 95N-0259
Over-the-Counter Human Drugs; Proposed Labeling
(62 Fed. Reg. 9024 (February 27, 1997))

Dear Dr. Friedman:

The American Association of Retired Persons (AARP) appreciates this opportunity to comment on proposed rules for over-the-counter (OTC) drug labeling developed by the Food and Drug Administration (FDA).

General Background

The agency itself has acknowledged the importance of OTC drug labels that are readable and understandable to older persons: in the proposed rule, FDA noted that the elderly comprise 12-17 percent of the population as a whole, but consume about 30 percent of all medications. By the year 2000, they are projected to consume as much as 50 percent of all medications.¹

Our members have been frustrated for too long by labels they simply cannot read. We are not talking about promotional material on these labels but, rather, information about the proper use of and possible side effects from OTC drugs -- information that is critical to consumers' health and safety.

The Federal Food, Drug, and Cosmetic Act (FFDCA) contains very general language on drug label format. Section 502(c) of the FFDCA deems "misbranded" any drug label that contains "any word, statement, or other information . . . [that] is not prominently placed thereon with such conspicuousness . . . and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." Until now, regulations implementing this section have been equally general and, as a result, labels are written in small type, in all upper-case lettering, and in long paragraphs.

¹ 62 Fed. Reg. at 9027.

We applaud the agency for proposing label format regulations that include detailed requirements regarding type size and style, and other format elements. Once finalized, these regulations should produce more readable OTC drug labels. Similarly specific regulations that implemented the Nutrition Labeling and Education Act have produced more consumer-friendly nutrition labels. The agency has also endorsed voluntary guidelines for the provision of prescription drug information that include detailed provisions regarding the format of this information.²

Before addressing specific aspects of the proposal, the Association would like to address two important issues. The first is the issue of the "quantitative benefits" that should result from revised OTC labels or, the flip side, the costs of the proposed revisions to pharmaceutical companies. We are confident that the costs to pharmaceutical companies of revising OTC drug labels will be significantly outweighed by the benefits that these new labels will bring to consumers, in the form of lower health care costs and improved quality of life. When the overall costs of revising OTC drug labels are translated into the impact on individual product labels, they should be minimal (at most, a few pennies). Consumers will benefit much more than the few pennies it may cost for their OTC drugs if they come with readable, understandable labels. Moreover, we urge the agency to establish an effective date for the OTC drug label rules that gives manufacturers time to deplete their existing inventories and make the necessary changes to their product labels.

The second general issue of concern to us is the need for on-going research on and testing of OTC drug labels. We strongly support FDA's intention to conduct research on the revised OTC drug label formats, which will include a comparison of the new labels with existing labeling. The only way to determine whether redesigned OTC drug labels are more useful to consumers is to test them on real people. This testing should be done on an on-going basis, and changes should be made to the label format regulations in response to any findings from research and testing.

Comments on specific issues addressed in the proposal

- **OTC labels should be as uniform as possible.**

We agree with the agency that consumers will be more likely to read and understand OTC labels if the labels use uniform headings and subheadings presented in a standardized order. The need for uniform OTC labels is particularly compelling at a time when more and more prescription drugs are being changed to OTC status.

We support requiring that information appear in a set order on the label so that it will become

² Steering Committee for the Collaborative Development of a Long-Range Action Plan, Action Plan for the Provision of Useful Prescription Medicine Information (December 1996).

- **The label should read "Consult your doctor or pharmacist".**

The pharmacist is an important member of any consumer's health care team, and often knows more than doctors about particular drugs, how to use them and what possible side effects they may have. Since a significant percentage of OTC drug products are purchased at pharmacies, it makes sense to require that the OTC drug label reference both doctors and pharmacists.

- **FDA should simplify language used on OTC labels and eliminate unnecessary connecting terms.**

We support FDA's proposal to simplify the language used on OTC labels and eliminate the use of connecting terms. These revisions should help all consumers, particularly those with low literacy skills, better understand OTC drug labels.

- **Federal requirements for OTC drug labels should preempt inconsistent state and local labeling requirements.**

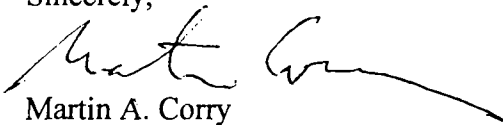
AARP agrees with FDA's tentative conclusion that inconsistent state and local labeling requirements should be preempted by federal provisions. Preemption is acceptable in this instance because the proposed federal rule provides sufficient consumer protection, and it would better ensure the uniformity of OTC drug labels.

Moreover, we support preemption here because FDA rules give states and localities the right to petition to be exempt from federal preemption based on particular local needs. In addition, federal preemption of OTC drug labeling does not at all limit state tort actions based on the format or content of OTC drug labels.

Conclusion

AARP applauds FDA for proposing regulations that should result in standardized OTC drug labels that are easily read and understood. The Association appreciates this opportunity to express our views. For further information on AARP's comments, please contact Tricia Smith of our Federal Affairs staff at (202) 434-3770.

Sincerely,



Martin A. Corry
Director
Federal Affairs

Attachment

NACDS

National Association of Chain Drug Stores

Thomas M. Ryan
Chairman of the Board

Ronald L. Ziegler
President & CEO

2102 '97 OCT -6 12:58

October 6, 1997

VIA HAND DELIVERY

Dockets Management Branch HFA-305
Food and Drug Administration
12420 Parklawn Dr. Rm 1-23
Rockville, MD. 20857

Re: Over-the-Counter Human Drugs: Proposed Labeling
Requirements: Extension of Comment Period [Docket Nos.
96N-0420, 92N-454A, 90P-0201, and 95N-0259] RIN 0910-
AA79

Ladies and Gentlemen:

The National Association of Chain Drug Stores (NACDS) submits the following comments in response to the Food and Drug Administration's (FDA's) proposed labeling requirements for Over-the-Counter (OTC) Human Drugs.

NACDS membership consists of more than 130 retail chain community pharmacy companies. Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 88,000 pharmacists. Chain community pharmacy is comprised of 18,700 traditional chain drug stores, 6,300 supermarket pharmacies and nearly 5,000 mass merchant pharmacies.

The NACDS membership base operates nearly 30,000 retail community pharmacies with annual sales totaling over \$125 billion, including prescription drugs and over-the-counter (OTC) medications. Chain-operated community retail pharmacies fill approximately 60 percent of the more than 2.6 billion prescriptions dispensed annually in the United States. Moreover 60 percent of the \$20 billion in OTC sales in 1996 were in chain community pharmacies, representing \$12.8 billion, or 16 percent of total sales.

Prepared by the National Association of Chain Drug Stores

October 6, 1997

Page 1

96N-0420

C 697

In general, NACDS commends the agency for its attempts to make OTC prescription drug labels more consumer friendly and easier to understand. An increasing number of prescription drug products are switching to OTC status. The availability of the products will increase the number of individuals who will effectively self treat minor medical conditions, which will likely result in better health and may lead to a reduction in overall health care costs.

On the other hand, the increased availability of products that were once prescription-status only, even if available in reduced doses, could result in additional adverse reaction and drug-related complications within the population if not taken appropriately, especially among older Americans. Therefore, public policy warrants that the agency also assure that the content of OTC labels encourage consumers to seek the advice of health care professionals on the appropriate use of these products. NACDS has three major policy areas of interest in the proposed regulation, which are further explained below.

I. Inclusion of the Term "Ask your Doctor or Pharmacist" on the OTC Label

NACDS supports the inclusion of the term "Ask your doctor or pharmacist" on the labels of OTC products. In our opinion, FDA effectively makes the case for the inclusion of such phrase on the label within the context of its proposed rule. Having said this, we believe that additional comments are unnecessary to justify including the term "pharmacist" on an OTC label. However, we offer our own justification here: Almost 60 percent of total annual OTC sales are made in retail pharmacies, where a pharmacist is available for consultation with the consumer. We believe that better therapeutic outcomes are attained if more, not less, advice, is provided to consumers by all health care professionals. Moreover, there are both public health and economic reasons for including this phrase "Ask your doctor or pharmacist" on the OTC package.

The importance of consumer interaction with a health professional about these products has become more important. That is because there have been a significant number of potent prescription medications that have been switched to OTC status over the last few years, with others likely to be switched over the next few years. The products that have already been switched include antihistamines, anti-ulcer medications, smoking cessation products, and topical antifungal products. Interactions of these products with other prescription drug products, foods, or disease states are just as likely if the product is designated as an over-the-counter drug as it is if the product remains on prescription-only status.



APhA

**American
Pharmaceutical
Association**

2215 Constitution Avenue, NW
Washington, DC 20037-2985
(202) 628-4410 Fax (202) 783-2351
<http://www.aphanet.org>

*The National Professional
Society of Pharmacists*

October 6, 1997

Dockets Management Branch
HFA-305
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857

2756 '97 OCT 14 P1:18

RE: Docket Nos. 96N-0420, 92N-454A, 90P-0201, and 95N-0259

Dear Sir/Madam:

The following comments from the American Pharmaceutical Association (APhA) reflect the views of America's pharmacy profession on the Food and Drug Administration (FDA) proposed rule published on February 27, 1997, pertaining to labeling requirements for Over the Counter (OTC) human drugs.

Need for Labeling Reform.

APhA recognizes the need for FDA's proposed rule changes. The number of products shifting from prescription-only to over the counter status has increased markedly over the past several years, providing consumers with more choices for self-care. These OTC products are increasingly available in a wide variety of retail environments, the fastest growing components of which do not provide the consumer with convenient access to a health care professional at the time when products are being considered and purchases are being made.

This lack of access to a health professional in settings where approximately 40% of OTC products are purchased places a greater burden of responsibility on the consumer for understanding and interpreting the product labeling, and for appropriate use of the medications. FDA has wisely chosen to modify its labeling requirements to support this unguided use, to improve the consistency, comprehensiveness, and comprehensibility of the labeling. In general, APhA believes that FDA has done a good job of proposing a format which will highlight the most important information for each product. The following comments detail some areas in which APhA recommends strengthening the proposed approach.

Standardized OTC Labeling Format.

A timely study of industry labeling practices appears in the September/October issue of the *Journal of the American Pharmaceutical Association* (copy of galley attached). The authors

96N-0420

C 941

American Medical Association

Physicians dedicated to the health of America



P. John Seward, MD
Executive Vice President

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax

October 6, 1997

Dockets Management Branch
(HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, Maryland 20857

RE: Over-The-Counter Human Drugs; Proposed Labeling Requirements [Docket Nos. 96N-0420, 92N-454A, 90P-0201, and 95N-0259]

The American Medical Association (AMA), representing 300,000 physicians and medical students, appreciates the opportunity to submit written comments on the Food and Drug Administration's (FDA) Proposed rule, "Over-the-Counter Human Drugs; Proposed Labeling Requirements" (*Federal Register* 62: 9024-9062, [February 27] 1997).

The AMA commends the FDA for undertaking this proposal to establish a standardized format for the labeling of all marketed over-the-counter (OTC) drug products. Because more consumers are engaging in self-medication with OTC products, some of which were formerly available only by prescription, it is increasingly important that consumers read and understand the information contained in OTC drug labeling. Furthermore, because current OTC product labels vary considerably with respect to design and format, consumers may have difficulty in reading and understanding this information, and in making reasoned decisions about the drugs they take. The proposed labeling requirements will enable many consumers to better read and understand OTC drug product labeling, developments that will contribute to safer and more effective use of OTC drug products. While we generally support much of the Proposed rule, we would like to share our concerns, as well, regarding the potential effect on patient safety.

The AMA generally supports provisions of the proposed labeling requirements for content and order of sections proposed in Part 201.66(c)(1) through (c)(7), including the proposal to list "Other Ingredients" or "Inactive Ingredients." The latter is important because many drug formulations contain lactose or other sugars, dyes, preservatives and binders that can cause gastrointestinal or allergic reactions in susceptible patients. The inclusion of an expiration date on the container also is desirable. However, the AMA believes it is unnecessary and possibly confusing to have a special heading for "Dietary Information" that would comprise information on the quantity of sodium, calcium, magnesium, and potassium contained in the dosage form. If quantities of these cations are judged to be significant, this information could be listed under the heading "Other Information."

150 Years of Caring for the Country

96N-0420 1847 • 1997

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CONSUMER HEALTH INFORMATION CORPORATION

8300 Greensboro Drive • Suite 1220 • McLean, Virginia 22102-3604

Phone (703) 734-6650 • Fax (703) 734-1459

COMMENTS OF CONSUMER HEALTH INFORMATION CORPORATION

ON

PROPOSED FDA LABELING REQUIREMENTS

OVER-THE-COUNTER HUMAN DRUGS

OCTOBER 3, 1997

These comments are written in response to the proposed labeling requirements set forth by the Food and Drug Administration (FDA) (Docket Nos. 96N-0420, 92N-454A, 90P-0201, and 95N-0259 "Over-The-Counter Human Drugs. Proposed Labeling Requirements"), calling for the establishment of a standardized format for labeling of over-the-counter (OTC) drug products. Consumer Health Information Corporation would like to compliment the FDA for addressing some of the very critical issues that impact the safe and effective usage of OTC's by consumers.

Consumer Health Information Corporation was founded in 1983. The company specializes in the development of patient education programs that help people better manage their prescription and nonprescription medications. Consumer Health Information Corporation is a privately-owned company and we develop a wide-variety of patient education programs for health care companies, including the pharmaceutical industry. We have worked with many pharmaceutical companies during their internal legal and regulatory reviews. As a result, we are familiar with how the FDA labeling requirements impact the development of patient education programs for both prescription and nonprescription medications.

We applaud the FDA for recognizing the importance of readability and design in OTC package labels. There are many benefits associated with standardizing the format of OTC package labels. However, FDA's proposed methods of standardization do not address all of the concerns consumers face when purchasing and using OTC products. Furthermore, while there are many benefits to standardizing the format of OTC package labels, there are severe limitations to the amount and type of information that can be placed on a label.

These copies are
OFFICIAL FDA Copies
not desk copies.

September 30, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville, MD 20857



**RE: Over-the-Counter Human Drugs; Proposed Labeling Requirements
[Docket No. 96N-0420, 92N-454A, 90P-0201, and 95N-0259]**

As a leading worldwide human healthcare product company, Merck & Co., Inc. has been a strong supporter of initiatives and concepts aimed at increasing the appropriate use of medicines in both the prescription and non-prescription environments. We are invested in a joint venture, *Johnson & Johnson-Merck Consumer Pharmaceuticals*, that specializes in providing over-the-counter (OTC) drug products to consumers worldwide.

We commend the Food and Drug Administration, hereafter referred to as the FDA or the Agency, for the efforts put forth in developing a comprehensive approach to a consistent and informative format for OTC drug labels. We recognize that such proposals often lead to a range of challenges and refinements before they can be effectively implemented, while maintaining the original intent. Thus, we are very interested in commenting on this FDA proposal to standardize the labeling for OTC products, hereafter referred to as The Proposed Rule.

Additionally, as a manufacturer of OTC drug products, we produce OTC labeling for all products and we often prepare specialized package inserts as well. Consequently, we are well qualified to comment on this topic and this letter provides our observations and recommendations on The Proposed Rule.

Our responses are organized under four main sections. First, we provide general comments on the scope of this Rule. Second, we provide responses to those topics where the Agency has specifically requested comment within the text of the *Federal Register* (FR) notice. Third, comments on the proposed language for the Code of Federal Regulations are provided, followed by a fourth section on areas which may require additional clarification which the Agency should consider in finalizing The Proposed Rule.

96N-0420

C 618

**DIVISION OF DRUG MARKETING, ADVERTISING AND COMMUNICATION
CENTER FOR DRUG EVALUATION AND RESEARCH
FOOD AND DRUG ADMINISTRATION
FAX TRANSMITTAL**

DATE: March 10, 1999
TO: Devora Adler
PHONE: 202-456-5707
FAX: 202-456-5557
FROM: **KATHRYN J. AIKIN, PH.D.**
5600 FISHERS LANE ROCKVILLE, MD 20857
ROOM: 17B04 **MAIL CODE: HFD-40**
PHONE: 301-827-2828 **FAX: 301-594-6759**
SECRETARY: LAURA RIDDLE

REMARKS:

Devora,
Enclosed is a brief summary of Studies A & B. These studies are part of the OTC Labeling Rule. Please feel free to contact me if you require further information.
-Kit Aikin

NUMBER OF PAGES INCLUDING COVER SHEET: 5

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probability that the information graphically identified as important is subject to more complete processing, leading to increased communication of this information.

The agency believes that the two studies it conducted helped to confirm that the new labeling format will significantly increase communication of OTC drug product information to consumers.

START

A. Study A

Study A was designed to compare the proposed labeling format with a prototype of the existing format, and to test the use of highlighting on the communication of important labeling information, including directions for use and warnings.

The agency tested four variables: (1) Label format (old format vs. proposed format), (2) drug type (cough-cold vs. pain reliever), (3) the use of highlighting, and (4) consumer attention (divided vs. focused)^{1/}. Highlighting, label format, and drug type were varied in the design of the sample product label, and attention was varied through instructions given to the respondent. The study included 1,202 respondents in 8 geographically distributed shopping malls in the United States, with approximately equal numbers of respondents from each location. Respondents were asked to evaluate various presentations of label information on several OTC drug package samples and were asked questions about each label to determine their knowledge, opinions, and willingness to read the label.

1/ Study participants read a food label, then a drug label. About half of the people were told they would be asked questions about both labels (divided attention); other half were told they would be tested only on the drug label (focused attention).

The study demonstrated that the proposed new format took less time and was easier to read and understand than the current format. The new format helped respondents make more correct product use decisions that required a simple search for information in the labeling. Study respondents indicated a general preference for the proposed format and, when their attention was divided, respondents felt more confident in their ability to use the new format. In addition, the study demonstrated that when presented with labeling containing more highlighted elements, respondents preferred such labeling and rated it as easier to read and understand. Under conditions with more highlighting, respondents who were instructed to focus on the labeling made more correct product use decisions when these decisions required mental application of labeling information, compared to respondents whose attention was divided. When the labeling contained less highlighting, there was no difference in the number of correct product use decisions between respondents who had focused or divided attention.

The results from Study A suggest that consumers relying on OTC drug product information utilizing the new labeling format will be (1) more confident in their ability to use the information in the labeling and (2) better able to make correct product use decisions.

B. Study B

Study B was designed to examine preferences for OTC drug product labeling formats by incorporating several design variations. Four variables were tested: (1) The order of the "Warning(s)" and "Direction(s)" section in the label (i.e., warnings before directions vs. warnings after directions), (2) the placement of the "Active ingredients" section at the top of the label vs. bottom of the label, (3) the use of a title as an introduction to the required labeling information ("Medication Facts" vs. no title), and (4) the use of dividing lines between sections (thick vs. thin lines).

This study included 904 respondents in 8 geographically distributed shopping malls in the U.S., with approximately equal numbers of respondents from each location. The respondents were asked to evaluate 16 label variations of either a sample cough-cold or sunscreen drug product. The respondents were also asked to rank the randomly ordered labels from most to least preferred, to specify the reason(s) for their first and second choices, and to rate a current OTC drug product label that ^{was} ~~is~~ not in the new labeling format. ✓

Overall, this study demonstrated that respondents preferred a title as an introduction and visual cue to the required labeling information. Labels with the title were viewed as more credible and readable than labels with no title. When asked why they preferred the label ranked as number one, the respondents indicated that they liked the layout because it: (1) Was easy

to read (16.7 percent), (2) begins with "Medication Facts" (14.6 percent), and (3) has "Medication Facts in bold/large print" and "Warnings" first/at top/under "Medication Facts" (17 percent). When the impact of all four design variables was analyzed simultaneously, the introductory title had the greatest relative impact on preference rankings.

With respect to the other variables the agency tested in Study B, preferences were much less impressive. These findings are addressed in other parts of this document that discuss each of these subjects. (See sections IV.A., IV.C., and IV.D. of this document.)

IV. The Agency's Conclusions on the Comments

STOP

A. Scope--§ 201.66(a)

Section 201.66(a) states that the content and format requirements in § 201.66 apply to the labeling of OTC drug products marketed pursuant to a final OTC drug monograph, an approved new drug (NDA) or abbreviated new drug (ANDA) application under section 505 (21 U.S.C. 355) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 331(1)), and products marketed where there is no final OTC drug monograph or application and the product is not subject to an ongoing OTC drug review rulemaking.

1. Several comments asked that § 201.66 not apply to homeopathic drug products, including those products listed in the Homeopathic Pharmacopeia of the United States as well as those not so listed. One comment, however, recommended that the

**COMMENTS OF
NATIONAL CONSUMERS LEAGUE
REGARDING PROPOSED RULE ON
OVER-THE-COUNTER HUMAN DRUGS; PROPOSED LABELING REQUIREMENTS
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
[DOCKET NOS. 96N-0420, 92N-454A, 90P-0201, AND 95N-0259]
SEPTEMBER 23, 1997**

The National Consumers League is a national nonprofit consumer organization that has represented consumers and workers in the marketplace and workplace for nearly 100 years. Assuring that consumers can purchase safe and effective medication is of primary concern to our organization.

The National Consumers League supports FDA's proposed labeling requirements for over-the-counter (OTC) drug products. As consumers assume greater responsibility for their own health, and as more drugs become available over-the-counter, consumers must be provided with easy-to-read and understandable information on the drug label. While the League applauds FDA's efforts in this area, we have some comments on ways to make labels even more consumer-friendly.

I. Consumers Are Assuming Greater Responsibility for Their Own Health

There is an increasing need for consumers to have easily readable and understandable information about OTC drugs. Information on *active ingredients, warnings, contraindications, directions, purposes, and other information* must be legible and accessible as OTC drug products are now widely available and used without medical supervision, and as more potent drugs have been switched from prescription to OTC status. Furthermore, consumers are

GIBBONS & COMPANY

1455 PENNSYLVANIA AVENUE, N.W.

THE WILLARD OFFICE BUILDING

SUITE 525

WASHINGTON, D.C. 20004

TEL (202) 783-6000

FAX (202) 783-4171

April 13, 1999

Mr. Christopher C. Jennings
Deputy Assistant to the President for Health Policy
Executive Office of the President
216 Old Executive Office Building
Washington, DC 20500

Dear Chris:

In my letter of April 7th I mentioned that I would keep you posted on the Congressional response to the proposed new OTC federal labeling regulations for sunscreen products and cosmetic products containing sunscreen protection. Enclosed is a copy of the letter sent last Friday to FDA Commissioner Henney by Senator Reed (D-RI) and Senator Dodd (D-CT) concerning the pending FDA sunscreen labeling regulations. Senator Reed was the sponsor of the May '99 effective date provision for the new federal sunscreen labeling requirements in the Food and Drug Administration Modernization Act.

As you can see from the letter, both Senators Reed and Dodd have serious concerns that these regulations will have adverse consumer effects and are urging the FDA to continue working toward a comprehensive sunscreen label that provides accurate and complete information about the full dangers of sun exposure and the health benefits of sunscreen products.

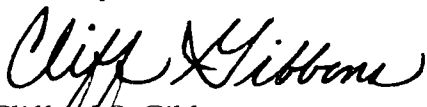
Later this week, Playtex will file a stay petition with the FDA on the proposed sunscreen labeling regulations. The filing of this stay petition exhausts all administrative remedies available for review of the proposed FDA labeling rules. However, we are not optimistic that FDA will pay much attention to the stay petition. From a public health policy perspective, we ask for your help in realigning this process so FDA can issue a single comprehensive labeling regulation and avoid further consumer confusion about sunscreen protection.

Mr. Christopher C. Jennings
April 13, 1999
Page 2

While I understand that you are unable to meet with me because the proposed labeling regulation is theoretically still in an agency rulemaking process, I wanted to make sure that you were fully informed as to how key Members of Congress view the FDA's proposed sunscreen labeling regulations. If I can provide further information please let me know.

Thank you.

Sincerely,


Clifford S. Gibbons

Enclosure

Re: Good article in Monday's Roll Call!

JACK REED
Rhode Island

COMMITTEES

ARMED SERVICES
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LABOR AND HUMAN RESOURCES
AGING

United States Senate

WASHINGTON, DC 20510-3903

March 30, 1999

Dr. Jane Henney
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Commissioner Henney:

We write to express concern about the impending publication of the Food and Drug Administration's (FDA) over-the-counter (OTC) sunscreen monograph.

Under P.L. 105-115, Food and Drug Administration Modernization and Accountability Act of 1997, the FDA was required within 18-months of passage of the Act (May 1999) to advance its sunscreen regulations. The provision was intended to encourage the agency to work toward completing its rulemaking process with regard to sunscreen products. As you know, the FDA has been involved in developing a final monograph for this category of OTC products since the 1970's.

We are concerned the forthcoming monograph only addresses ultraviolet B (UVB) radiation protection. Indeed, by not addressing the potential dangers of ultraviolet A (UVA) radiation, we fear the monograph will create confusion or a false sense of security among consumers who use sunscreen products. The National Consumers League is also concerned that the monograph may compromise consumer health and safety by undermining consumer understanding of the need for sunscreen products.

The initial comment period for the proposed final monograph, which was published in the Federal Register in May 1993, elicited a number of consumer-related concerns ranging from the deficiencies in pediatric labeling, to the arbitrariness of the Sun Protection Factor (SPF) scale range. Specifically, the Environmental Protection Agency (EPA) comments highlighted concerns that consumers wishing to protect themselves from undue sun exposure may not have sufficient information if the label only relates to SPF, which only addresses UVB radiation. However, since the 1993-94 comment period, the proposed final monograph has not been comprehensively reviewed to incorporate new insights or information that could be of significant value to the monograph.

We understand that the FDA is developing a separate procedure for evaluating UVA radiation, its effects, appropriate forms of protection, and how best to provide UVA information to consumers. In this regard, we would encourage you to continue your efforts to foster extensive public discussion among interested parties as you address these issues.

PLEASE RESPOND TO:

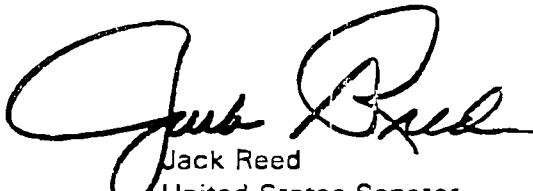
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- www.senate.gov/~reed

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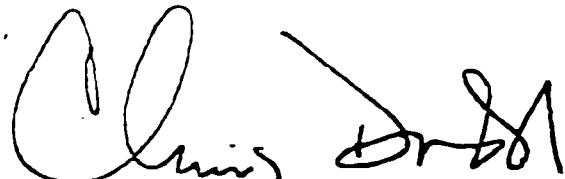
Meanwhile, we would also urge you to continue working toward a comprehensive sunscreen monograph that provides accurate and complete information about the full dangers of sun exposure and the benefits of sunscreen products. It is our view that publishing a final monograph at this time that does not address the full risk of sun exposure from both UVA and UVB could result in sunscreen labeling that unintentionally misinforms consumers about the level and type of protection that sunscreen products provide and how best to use them.

Thank you for your attention to these concerns.

Sincerely,



Jack Reed
United States Senator



Christopher J. Dodd
United States Senator

American Academy of Pediatrics



Department of Government Liaison
American Academy of Pediatrics
The Homer Building
601 Thirteenth Street, NW
Suite 400 North
Washington, DC 20005
202/347-8600
800/336-5475
Fax: 202/393-6137
Internet: kids1st@aap.org

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October 6, 1997

Dockets Management Branch (HFA-305)
Food and Drug Administration '97 OCT -6 P3:48
12420 Parklawn Drive, Rm 1-23
Rockville, MD 20857

**RE: Over-The-Counter Human Drugs; Proposed Labeling Requirements
[21 CFR Parts 201, 330, and 358]**

Dear Sir/Madam:

The American Academy of Pediatrics (AAP) appreciates the opportunity to comment on the proposed over-the-counter (OTC) drug product labeling changes as published in the Federal Register of February 27, 1997 (62 FR 9024-9062). The Academy supports the agency's objectives towards improvement in OTC product labeling that will afford consumers easier to read and understandable information concerning the safe and effective use of such products. Specific comments are based on the health interests of children which represent a significant segment of the overall OTC drug product market.

As stated in section III of the supplementary information, the growing trend towards moving drugs from prescription to OTC status, the increasing tendency for consumers to become more actively involved in their own health care and practice self medication, and the economic and commercial realities which drive changing patterns of OTC drug use, represent a significant challenge to the agency to ensure that all consumers are offered the therapeutic benefits of efficacious drug products in accordance with strict standards of safety. Whereas the rule acknowledges safety profile as a key determinant in Rx to OTC switch decisions, it remains imperative for the agency to consider the routine assessment of safety profile data for drugs with use or potential use in children. A prescription drug that has been on the market for a substantial period of time with approved labeling for use in adults does not answer safety profile questions for children. An informal survey of selected drugs undergoing a status change between 1976 and 1996 reveals the following:

- Only 28% of prescription drugs participating in an OTC switch had pediatric labeling whereas even fewer of OTC switched drugs (7%) had labeling for children of all ages except infants.
- As compared to prescription status, more OTC switch drugs had a higher disclaimer age, usually children under 12 years.
- A trend for same or higher disclaimer age was noted when paired comparisons of prescription to corresponding OTC switch drugs was made.

C 9/15

96N-0420