＜インタビューを通じてOTC薬による副作用被害に対する私信＞

OTC薬の使用は、消費者が容易に手に入れことができること（利便性）と低コストが消費者のメリットになっている。一方で、これにはOTC薬による副作用被害のリスクが伴うという矛盾が生じる。特にスイッチOTC薬の使用に関しては、薬剤師が介入することにより、副作用被害を軽減できると思われるが、薬剤師による消費者への教育・指導については薬剤師によるボランティアとしてではなく、法的な規制・措置が必要であると思われる。

写真 1

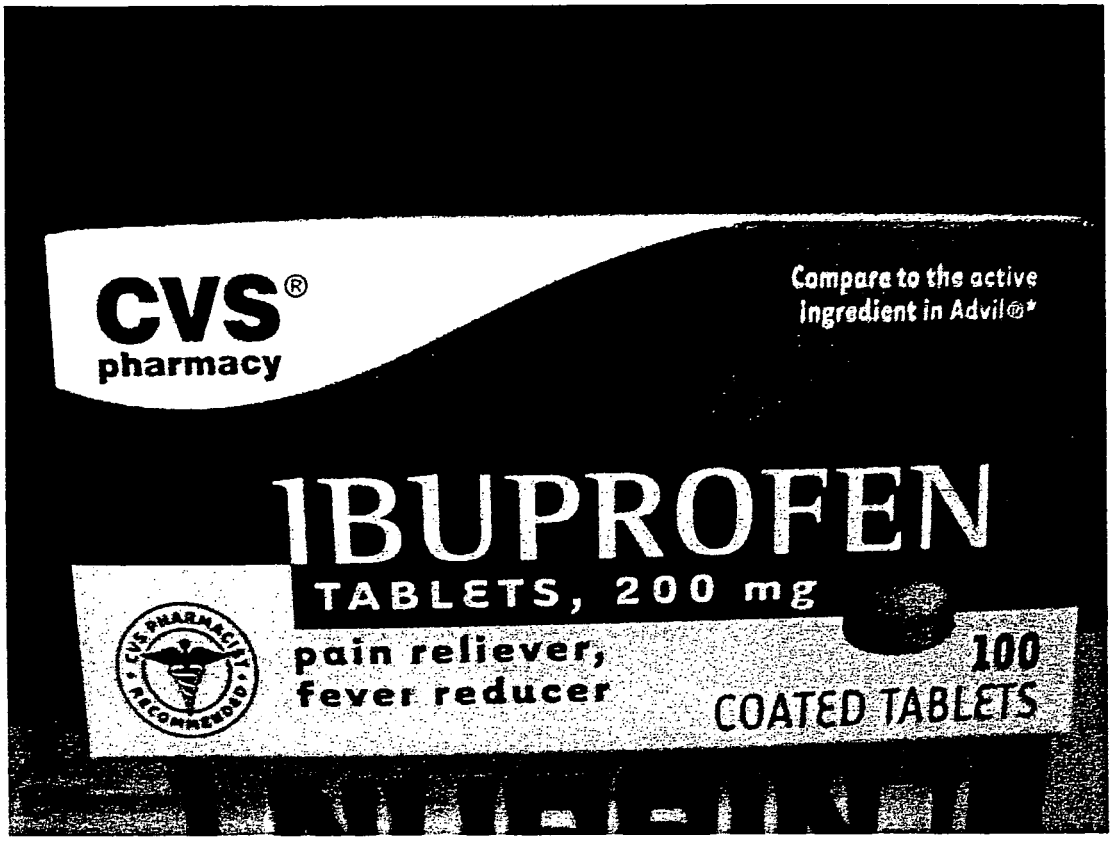

CVS®
pharmacy
Compare to the active ingredient in Advil®*
IBUPROFEN
TABLETS, 200 mg
pain reliever,
fever reducer
100
COATED TABLETS

写真 2

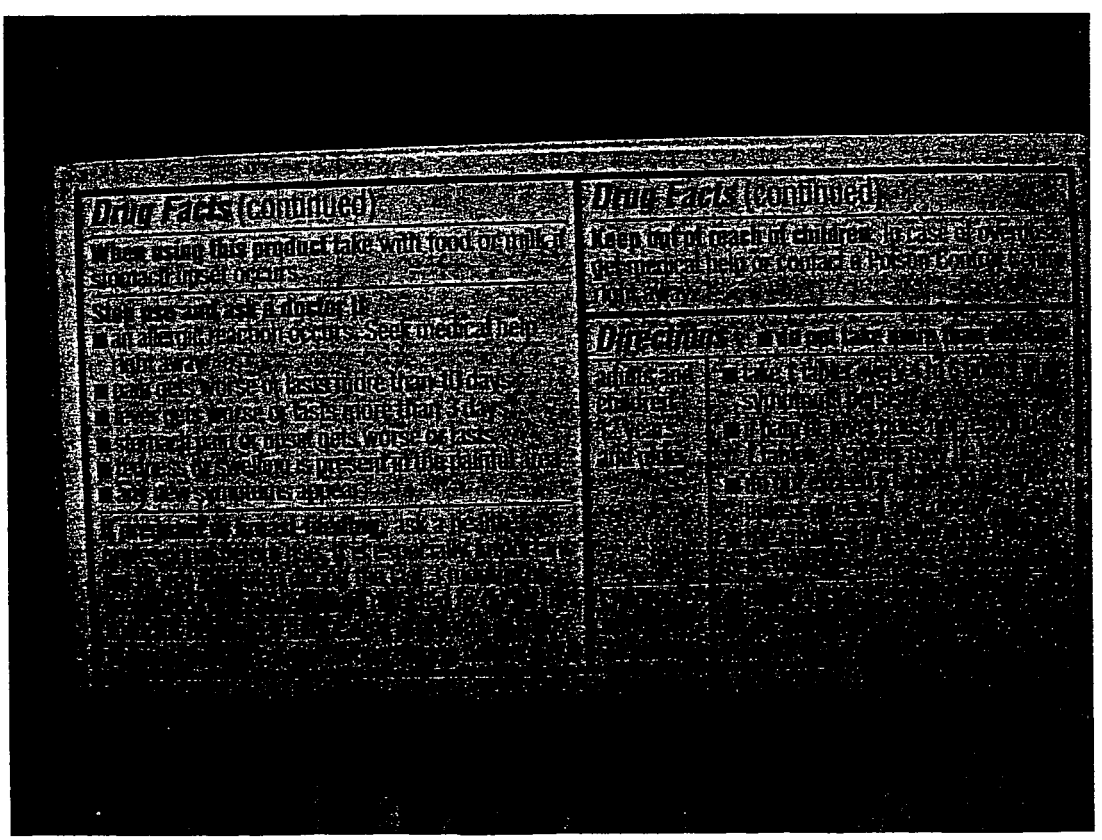
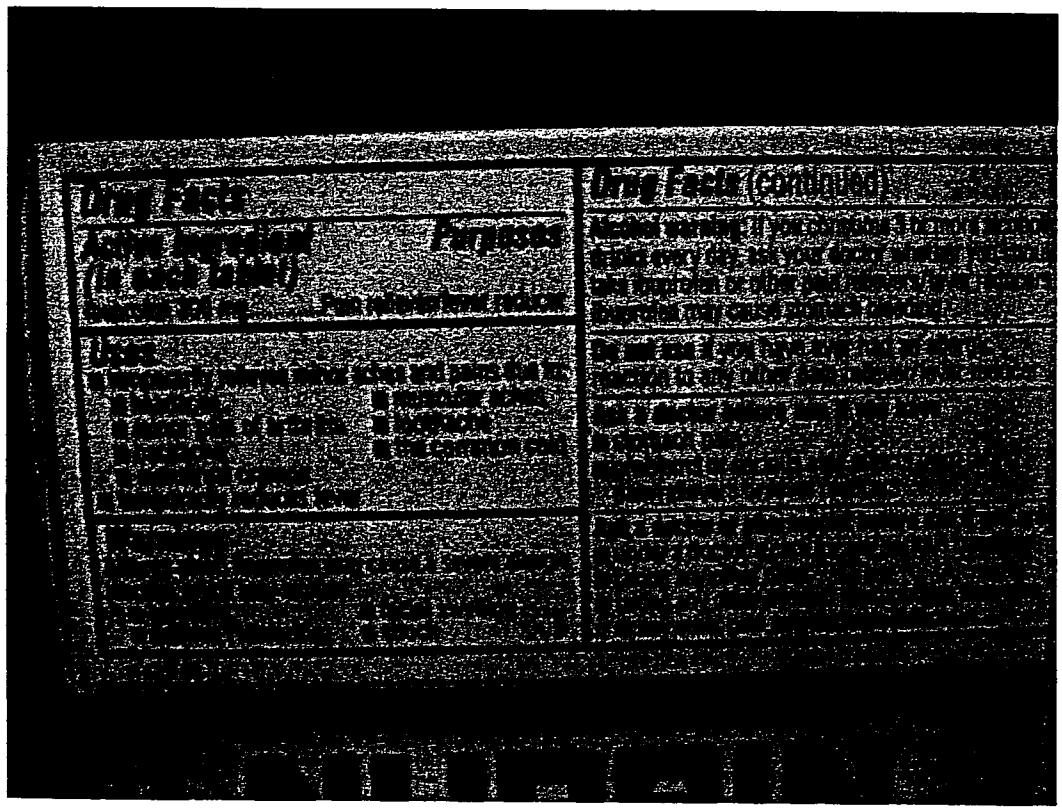

Drug Facts (continued)
When using this product take with food or milk if
Drug Facts (continued)
Keep out of reach of children.

写真３



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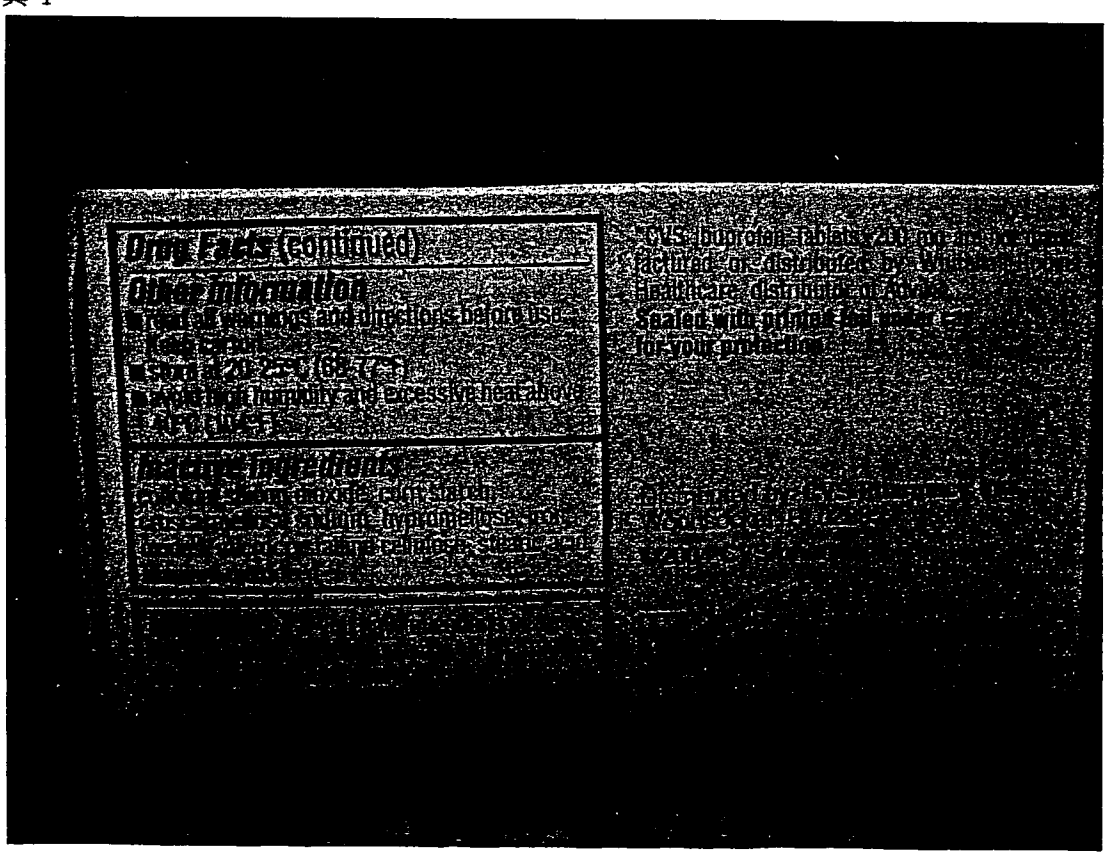

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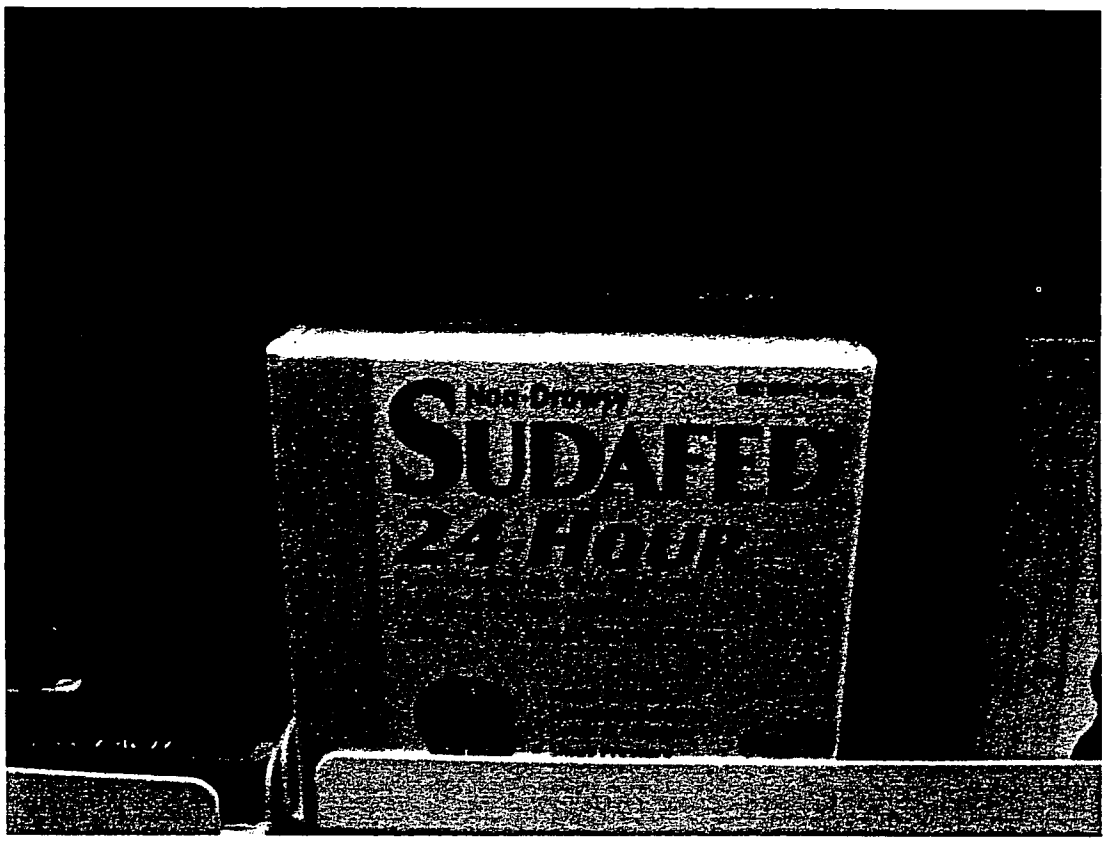

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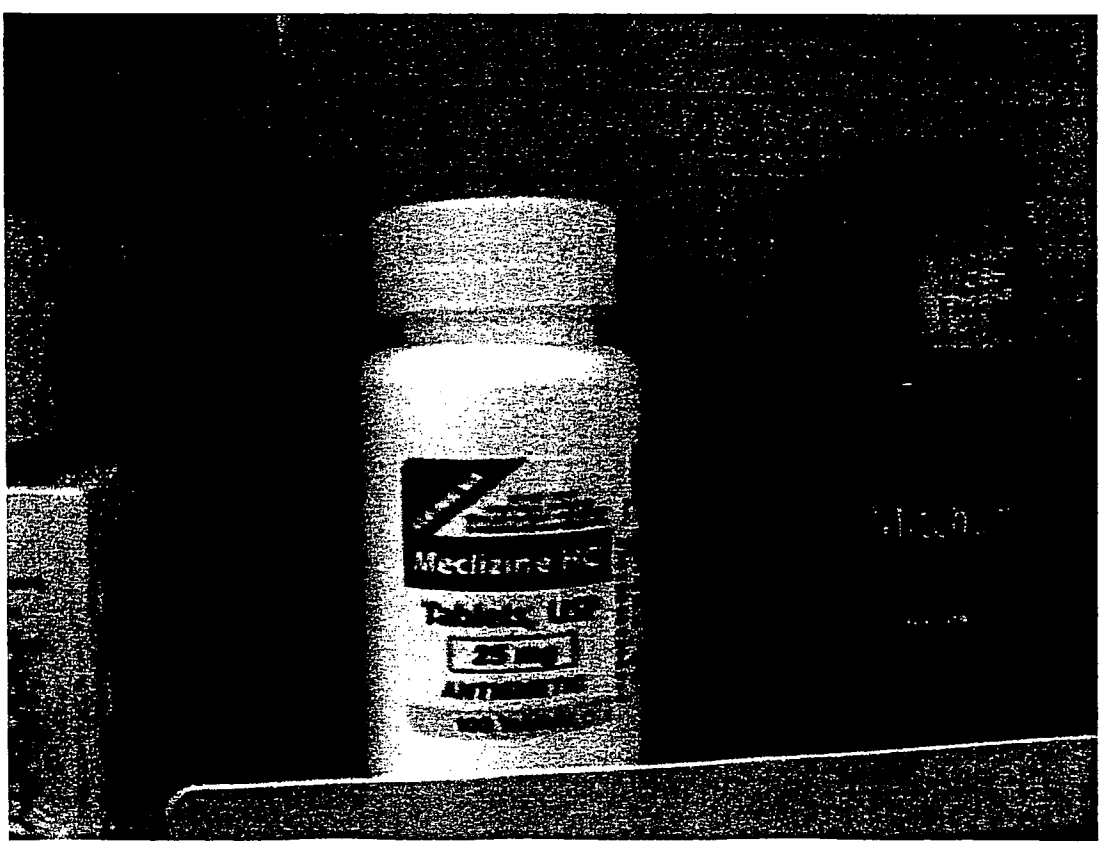


写真７

写真８

写真９

写真１０

写真１１

写真１２

写真１３


FOOT CARE
DIABETES CARE
HOME DIAGNOSTICS
FIRST AID
Pharmacy
pharmacists who care
new!

写真１４

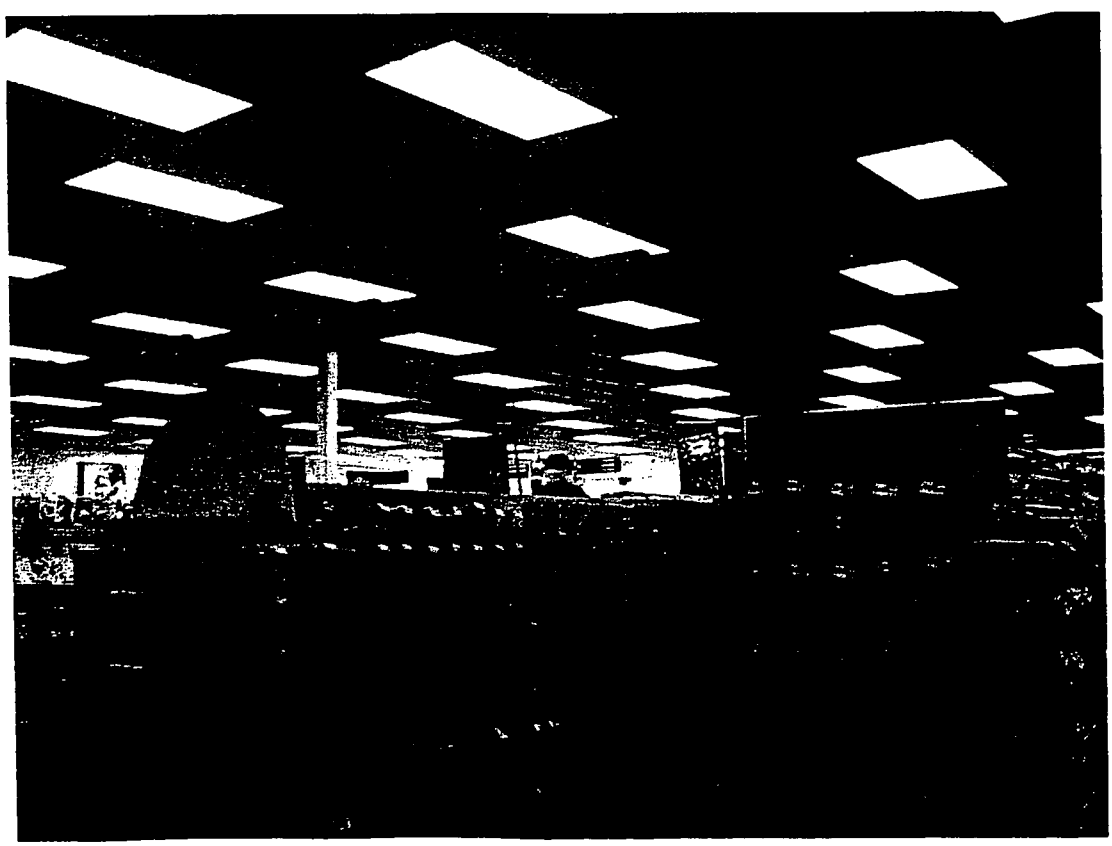


写真１５

写真１６　薬局の中からの写真

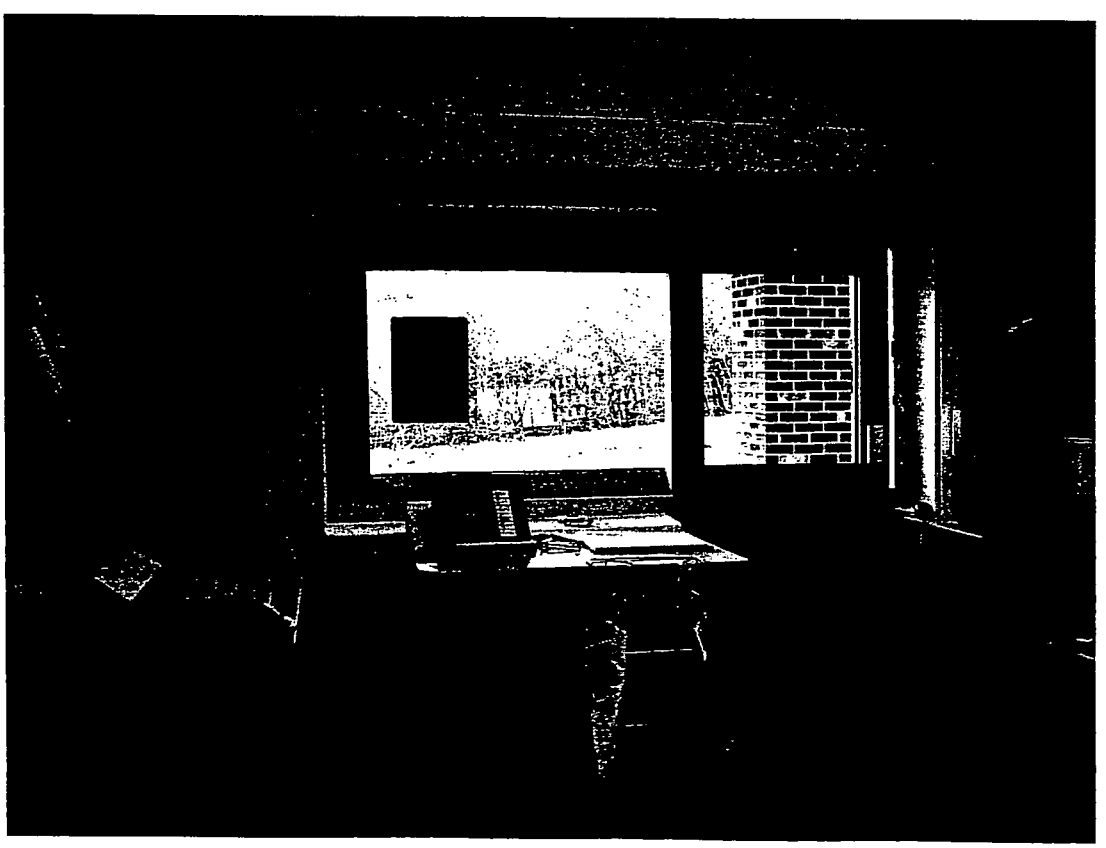
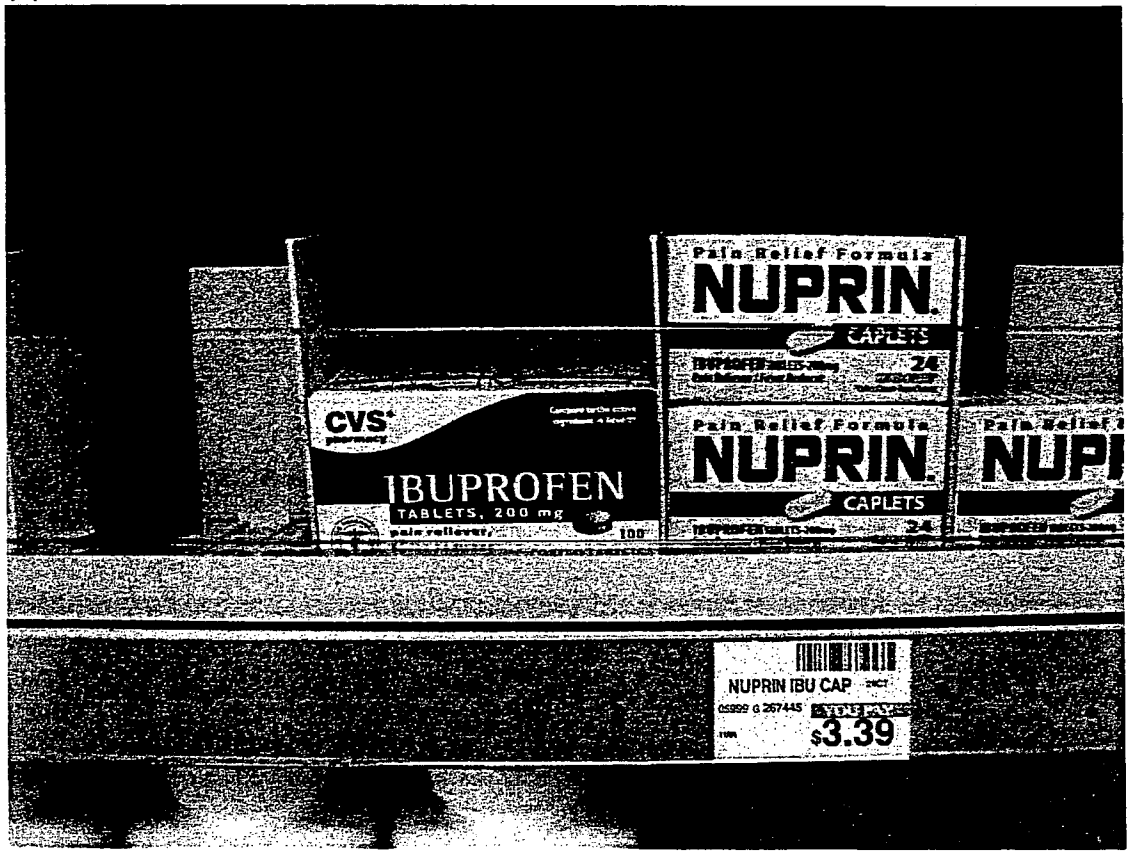


写真１７

写真１８

写真１９


Pain Relief Formula
NUPRIN
CAPLETS
24
CVS
IBUPROFEN
TABLETS, 200 mg
100
Pain Relief Formula
NUPRIN
CAPLETS
24
NUPRIN IBU CAP
$3.39

資料1

HANDBOOK OF NONPRESCRIPTION DRUGS

An Interactive Approach to Self-Care

fourteenth edition

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Editor: *Karen J. Tietze*

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Foreword

Self-care is defined by the World Health Organization (WHO) as "those activities that individuals, families, and communities undertake with the intention of enhancing health, preventing disease, limiting illness, and restoring health." These activities can be initiated by individuals on their own behalf or recommended by health care professionals. (The pharmacist's role in self-care is discussed at http://www.who.int/medicines/library/dap/who-dap-98-13/who-dap-98-13.pdf. Accessed December 15, 2003.) Self-care should be viewed as a continuum of self-initiated behaviors that enhance the health and independent functioning of individuals, rather than as a failure of the individual to use professional medical services. Self-care behaviors can be classified as (1) healthful lifestyle behaviors intended to promote health and prevent disease, (2) medical self-care behaviors that relate to symptoms and treatment, and (3) behaviors that relate to improving quality of life and daily living in individuals with disabling limitations associated with physical or cognitive function, or chronic disease. The use of nonprescription medications, complementary and alternative therapies, nondrug measures, diagnostic tests, and medical devices are integral parts of self-care.

Today, many individuals take an active role in their own health care. Numerous factors have contributed to the growing self-care movement in the United States, including an increase in direct-to-consumer advertising of prescription and nonprescription medications. Information obtained from television commercials, newspaper and magazine advertisements, the Internet, and health-related articles serves to empower the consumer to make decisions about their own health care. However, individuals embracing self-care may not have adequate information to determine if their medical condition is amenable to self-treatment and if the self-selected treatments are appropriate for the condition.

Individuals who wish to self-treat minor health disorders are faced with a staggering number of single-entity and combination nonprescription products. The Consumer Healthcare Products Association indicates that "retail sales of nonprescription medications in the United States in 2002 exceeded $17.2 billion, reflecting an increase from $2.9 billion in 1971. (See http://www.chpa-info.org/statistics/OTC_Retail_Sales.asp for further information. Accessed December 15, 2003.) Other similar surveys confirm the increased use of nonprescription medications. Sales may be boosted further by the Internal Revenue Service Revenue Ruling 2003-102, which went into effect October 1, 2003. This ruling allows employers to reimburse properly substantiated nonprescription medication expenses, but not dietary supplements, from flexible health care spending accounts. (See http://www.irs.gov/pub/irs-drop/rr-03-102.pdf for the full text of the ruling. Accessed December 15, 2003.)

The anticipated increase in the number of prescription medications that will be reclassified as nonprescription will further confound the patient's dilemma in selecting appropriate self-treatment. All health care practitioners should be able to assist individuals in the management of their own self-care. However, pharmacists, because of their accessibility and expertise with respect to nonprescription and prescription medications, are in a unique position to fulfill the self-care needs of most individuals with minor health ailments.

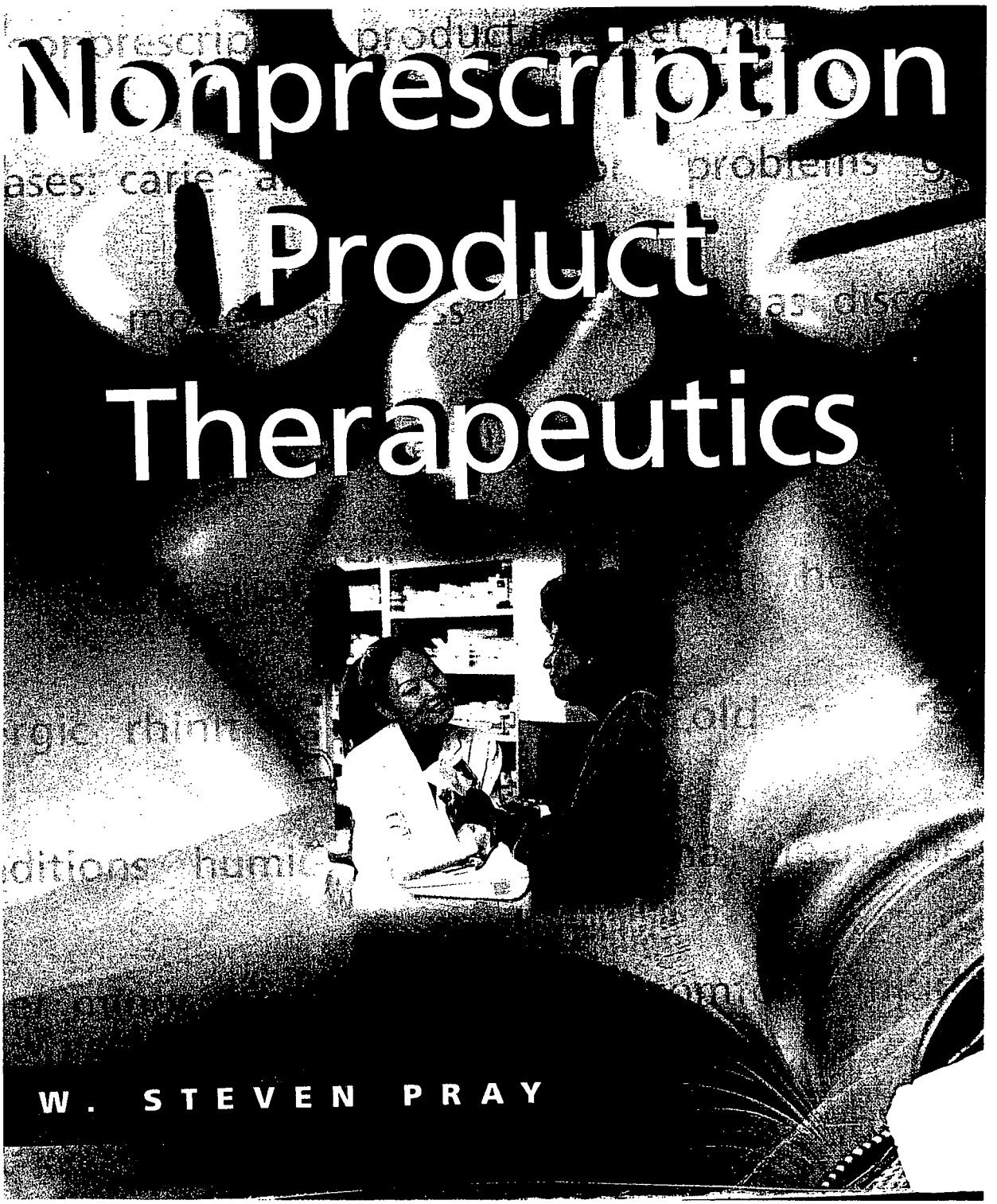
Complementary medicines (e.g., botanical and nonbotanical natural medicines) and alternative therapies (e.g., homeopathic remedies) are also experiencing exponential growth in the United States and reflect societal changes in attitude toward natural and preventive medicine. Patients use these therapies as (1) adjuncts to conventional prescription medications, (2) treatment for minor health conditions, and (3) preventive measures to foster good health. In the past, complementary and alternative medicines have been primarily distributed through health food stores and by mail order. However, these therapies are sold in mainstream mass-market outlets today, including grocery stores and pharmacies. Unlike nonprescription medications, however, no federal regulatory agency evaluates the safety and effectiveness of complementary and alternative therapies.

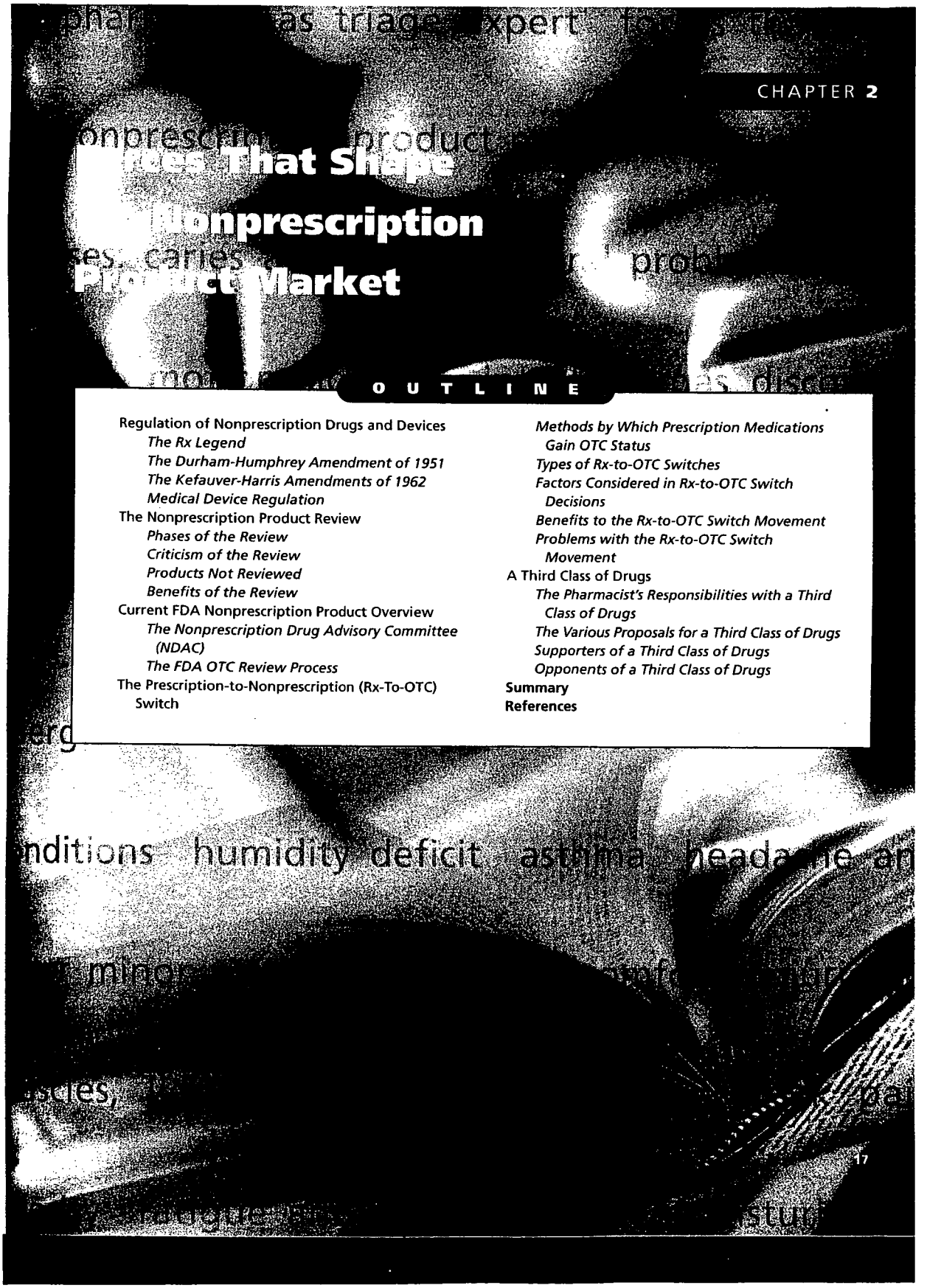
Homeopathic therapies, another alternative to traditional medicine, have been used for years in this country. In the past, most homeopathic products were distributed through health food stores and by mail order. Today, homeopathic therapies are regulated by the federal government, homeopathic manufacturers are subject to inspection—as are the conventional pharmaceutical companies—and there is an official homeopathic national formulary.

The increased use of complementary and alternative medicines—as well as the paucity of clinical evidence as to their safety and effectiveness, and the potential for serious adverse events when these products are combined with each other or with nonprescription and prescription medications—demand that health care practitioners be knowledgeable about alternatives to traditional medications and be able to provide therapeutic information and guidance to the consumer.

John A. Gans
Executive Vice President & CEO
American Pharmacists Association

資料２





CHAPTER 2

That Shape Nonprescription Product Market

OUTLINE

The nonprescription product market is dynamic and ever-changing, with many older nonprescription drugs discontinued and many new OTC products introduced each year. Some of the new nonprescription products hold special challenges for pharmacists, because they were formerly limited to prescription status. To better understand the forces that shape this volatile market, this chapter examines the regulation of nonprescription drugs, the FDA's OTC review, the Rx-to-OTC switch phenomenon, and the national call for a third class of drugs.

REGULATION OF NONPRESCRIPTION DRUGS AND DEVICES

The Rx Legend

Prior to passage of the 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act) in 1938, the line between prescription and nonprescription products was nonexistent (although the Harrison Narcotic Act of 1914 had made narcotics prescription-only).[1] This legislation required that manufacturers submit a new drug application providing proof of safety prior to marketing medications.[2,3] It also required that adequate directions and warnings be provided on all drug labels, unless the label specifically carried a new prescription legend, "CAUTION: Federal Law Prohibits Dispensing Without Prescription."

There was no actual requirement that any medication carry the legend. As a result manufacturers opted to attempt to provide directions and warnings to allow self-use and were slow to adopt the legend. Thus many dangerous medications were labeled as though safe for self-use, and the distinctions between prescription and nonprescription products remained unclear during the ensuing 2 decades.

The Durham-Humphrey Amendment of 1951

In 1951 the Durham-Humphrey Amendment to the FD&C Act of 1938 attempted to further define nonprescription and prescription medications and to clarify the requirement for the Rx legend.[1,3] Products without the prescription-drug legend became known as "nonlegend" or nonprescription medications, a new class of medications now popularly known as "over-the-counter drugs" or OTCs.

The Kefauver-Harris Amendments of 1962

In 1962 the Kefauver-Harris Amendments to the FD&C Act mandated proof of effectiveness for prescription medications marketed after 1938.[2] (Medications marketed prior to 1938 are known as "grandfathered" drugs because, at that time, they were assigned GRASE [generally recognized as safe and effective] status.)

Medical Device Regulation

In 1976 the Medical Device Amendments to the FD&C Act clarified the marketing requirements of medical devices. According to this amendment manufacturers must notify the FDA at least 90 days before marketing a medical device for the first time.[2] If the application is simple, it is usually approved within the 90 days, although more complicated applications may require more time, causing the manufacturer to wait a longer period before marketing the device.[4]

THE NONPRESCRIPTION PRODUCT REVIEW

The Kefauver-Harris Amendments gave the FDA authority to review nonprescription drugs marketed after 1938 for proof of safety and efficacy. The FDA carefully considered the most appropriate method to use in this review. In 1972 the Food and Drug Administration began the review.[5,6] Because there were an estimated 300,000 nonprescription products to review, the agency quickly realized that the product-by-product method used for prescription products would not be feasible with OTCs. The FDA decided to facilitate the review by placing OTCs into therapeutic classes (e.g., antidiarrheals, antacids, otic products).[7] The subsequent OTC drug review, certainly one of the most comprehensive programs undertaken by FDA, proceeded in three phases[8]:

- Phase 1—Review panels evaluate products. "Advance Notice of Proposed Rulemaking" published for each therapeutic class.
- Phase 2—Deliberations for Category II and III ingredients. "Proposed Rule" or "Tentative Final Monograph" published for each therapeutic class.
- Phase 3—Deliberations continue for Category II and III ingredients. "Final Rule" or "Final Monograph" published for each therapeutic class.

Phases of the Review

PHASE 1

In Phase 1 of the review the FDA appointed an advisory review panel for each therapeutic class.[9,10] The advisory review panels were asked to amass data regarding the safety and efficacy of the ingredients included in products sold for that condition. Panels were made up of representatives from medical and scientific fields as voting members such as physicians, pharmacologists, toxicologists, and pharmacists and other professionals appropriate for that group of products (e.g., dentists or podiatrists).[11] Consumer and industry representatives could be included on panels but only as nonvoting members.[3] FDA employees too could be included on the panels but also not as voting members.

The review panels asked manufacturers to submit products for which review was desired. The advisory panel listed the various ingredients in products sold for that condition and then exhaustively searched for evidence of safety and efficacy. During the reviews the advisory panels examined 20,000 volumes of data concerning 1454 uses of 722 individual ingredients and held 508 meetings.[7,11]

The reviews concluded with the publication of a report, a