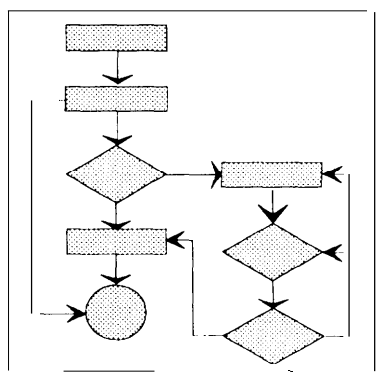
The OTA Survey and Evaluation Process 2

This study took a "snapshot" of drug labeling current between 1988 and 1990 and evaluated its medical appropriateness. Unlike previous drug labeling studies, which had approached the task by documenting problems with specific product labeling, OTA took a broader perspective and developed new methodology. This chapter describes the methods that were developed to select sample products, gather labeling material, and evaluate the information content of the labeling. The results of the analyses are presented in chapter 3.

SAMPLE SELECTION

Selection of Countries

The congressional requesters of this study stipulated that 8 countries be included from the 15 listed in their letter to OTA. OTA considered it important to represent different geographic areas and, to the extent possible, other country characteristics (e.g., level of development, cultural background). Panama and Brazil were selected for a pilot study based on OTA's judgment that they would be accessible for field visits and represented sizable markets for the products of U.S.-based pharmaceutical companies. As it turned out, it was not possible to arrange official visits to either country during the time of the pilot study. Product labeling was obtained from those countries, however, and procedures for evaluating the information were developed and tested.



In order to gauge the importance of field work to the project (visits to study countries were required by the request), a third country, Kenya, was chosen. Arrangements were made quickly for project staff to travel to Kenya in March 1988 for discussions with government, industry, and health sector representatives, and to collect labeling directly.

Experience with the evaluation process and the field visit made it clear that it would not be possible to carry out a thorough study in eight countries. The evaluation process is time-consuming and exacting of medical knowledge, both for OTA staff and for outside reviewers. Field visits require extensive planning and are expensive both in staff time and money. OTA therefore proposed to limit the study to four countries, including those already begun, adding one other in Southeast Asia, the other major market area. For reasons of market size and for the ease of conducting field work, Thailand was chosen. OTA staff visited Thailand in November 1989 to conduct interviews and collect labeling for a sample of products.

Identifying Relevant Companies

OTA identified the U.S.-based companies selling products in the study countries through the Pharmaceutical Manufacturers' Association (PMA). PMA was approached for this purpose after it had been determined that it was not possible to identify U.S.-based multinational pharmaceutical companies from any U.S. Government source, including the FDA and the Department of Commerce. In all, 19 companies were included. All are PMA members and are major research-based fins. Although it is possible that some companies were missed, based on examining prescribing guides and on scanning pharmacies for products, these 19 companies do account for the vast majority of U.S.-based pharmaceutical business in the study countries.

Selection of Sample Products

Over the course of the study, OTA asked each company to supply a complete list of their products marketed in Brazil, Kenya, Panama, and Thailand. Sampling of products for each country was carried out independently, and within each country, independent samples were drawn for each company. In total, 273 products were selected. The same sampling procedure was used for Panama and Brazil, and a slightly different one for Kenya and Thailand. Both procedures were designed to produce unbiased samples.

For Panama and Brazil, each company's complete list of products was first grouped by therapeutic category. The products within each category were alphabetized and numbered. Samples of between 20 and 25 percent of each company's products were selected by number within each therapeutic category using a random number generator.

For Kenya and Thailand, the lists of products were used as sampling frames in the order they were received from the companies. Again, samples of 20 to 25 percent were taken, using a "systematic sample." For each company, every fourth or fifth product listed was included. The companies had organized the lists in different ways, and OTA had specified no special order for them, so the systematic approach should not have introduced any bias.

No adjustments were made to the random or systematic samples to include or exclude specific products for any reason. No attempt was made to include "problem" products.

Throughout the course of the study and in this report, OTA has maintained as confidential the names of the sample products and the details of the evaluations. Only the Expert Review Group, OTA staff, and the companies themselves (each for their own products only) were privy to all the details. This was not done because the study involved privileged information, but because the particular products studied by OTA are a representative sample and do not themselves represent an important set of drugs.

OBTAINING PRODUCT LABELS

Early in the study, OTA asked the companies to send all labeling material (including packaging, package inserts, advertising, and promotional material) for all their products marketed in Panama and Brazil. This elicited a large volume of information, which was used to determine

what a reasonable sample size would be, and to examine the various types of material for their general content. Since there was no opportunity for field collection in Panama and Brazil, labels for the sampled products came directly from material submitted by the companies. Labeling material (packaging and inserts) for products in the Thailand and Kenya samples was obtained from pharmacies in those countries.

The original labeling sources were supplemented by the companies in response to queries sent to them after the original material (for Panama and Brazil, material provided by companies, and for Kenya and Thailand, the field-collected material) had been examined by the Expert Review Group (see below). Various updated inserts, inserts pending approval, and prescribing guide entries were submitted to OTA and these were used in subsequent analyses *providing they were in circulation or had been submitted to the country regulatory authority for approval at the time the Expert Review Group reviewed them. New* labels initiated after the relevant Expert Review Group workshop were not accepted for later review. This restriction was necessary because many changes were initiated by companies as a result of OTA'S initial queries. In a number of cases, companies sent their international product circulars, but these were not acceptable for the purposes of this study, as they would not be available routinely to practicing physicians.

OTA always evaluated the most comprehensive piece of labeling material that would be readily available to practicing physicians for each product in each country. Table 2-1 lists the information sources that were accepted for analysis, and each one is described briefly below.

Package Insert

Package inserts—fliers enclosed with each company-packaged bottle or box of product—generally contain more detailed information than other sources of labeling. In the United States, package inserts are virtually always included with over-the-counter (OTC) and prescription drugs. (See ch. 4 for the detailed requirements.) Their format is dictated by the U.S. Code of Federal Regulations, and their content must be approved by the FDA. Brazil, Kenya, and Thailand also require some type of package insert, but they are optional in Panama. In Thailand, many products contain both a Thai language and an English language insert, and others have English

Table 2-l—Sources of Labeling Material for OTA Analysis

Source	Description
Package insert pending approval	Insert submitted to local regulatory agency but not yet approved. Contains, on average, more complete information than insert then in current use.
Package insert	Fliers enclosed with each company-packaged bottle or box of product. Generally contains the most detailed information (when no new insert is pending approval).
Product label only	The composite of information printed on packages and bottle labels. Used only when no package insert was available.
Prescribing guide	A periodic publication distributed to physicians designed as a quick reference for availability y and prescribing information for pharmaceuticals. Used when no package insert was available.
Product datasheet	Also known as international product documents. This detailed source of product information is distributed to physicians and pharmacists by drug company representatives and is also available on request from the company.

SOURCE: Office of Technology Assessment, 1993.

or Thai inserts only. The Thai language inserts are often abridged compared with the English ones, so, when available, English inserts were used for analysis.

In some cases, companies informed OTA that they had submitted a request to the national drug regulatory authority for approval of updated labeling. In those cases, OTA asked the companies to document their claims, and when it was provided, the inserts pending approval were used for the analysis. In two instances, product documents were evaluated.[1]

Prescribing Guide Entries

Prescribing guides are periodic publications distributed to physicians in many countries, and often are the most readily available pharmaceutical reference. They are specific to individual countries or regions, and exist for each of the countries included in this study. The purpose of prescribing guides is stated by their publishers as being a quick reference to find out which drugs are available in a country or region and to provide brief prescribing information.

In most prescribing guides, general information about a class of drugs is given, followed by brief entries for each product in the class. A typical entry contains the trade name and generic name of the product, the manufacturer, a brief review of indications, contraindications, warnings, precautions, and dosing information, and a description of how the product is presented and packaged. The product-specific information is submitted to the publisher by the companies, but the publisher has editorial control, and may abridge the entry considerably. In this study, prescribing guide entries were used for just under half of the products from Panama and were also used as supplementary information when provided for drugs from Thailand and Brazil.

Package Labels and Boxes

When nothing else was available, the composite of information printed on packages and on bottle labels was used for analysis.

TRANSLATION OF FOREIGN LANGUAGE LABELING

All labeling to be evaluated from Panama and Brazil was translated into English by independent technical translators of Spanish and Portuguese, respectively, on contract to OTA. Labels from Kenya were all in English. Labels in Thai language were translated for OTA by a Thai pharmacy graduate student with English fluency. In a few cases, OTA asked the companies to provide translations from Thai.

THE LABELING EVALUATION PROCESS

The heart of the evaluation process was a review of the labels for "medically important" information by a group of outside experts. The sample drugs were discussed during the course of three 2-day meetings of this Expert Review Group. The "medical importance standard" was not applied by simply cataloging differences between the foreign labels and FDA-approved labels or some other standard. Each label was reviewed to determine whether it contained appropriate and sufficient information-essential medical information-for a physician to rely on to use the product safely and effectively. The process is described fully in the sections that follow.

Although details of each product evaluation are given in chapter 3, the products are not named, nor are the responsible companies or countries of sale. This presentation is meant to illustrate the nature of OTA's evaluation and rating system. Summary data from the sample are also presented in chapter 3.

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[1] At the beginning of the study, OTA agreed to evaluate the company product documents for two products that did not have package insert.% Later, however, OTA decided not to accept company product documents as a source of labeling for analysis be-cause product documents are not universally available to the physicians who use the product (they are often only available by request to the company or sometimes distributed by company detail men to physicians and pharmacists). Because OTA had previously agreed to evaluate the two product documents referred to, they remain in the analysis.

I OTA Preliminary Screen of Labels

OTA screened each label before the meeting at which it was to be discussed, as an aid to the Expert Review Group. The screen consisted of a section by section comparison of the sample label with some recognized standard, and the differences were listed on a summary form. Information is often organized differently on labels from different companies and in different counties, so the summaries were also useful in standardizing information groupings, regardless of where the information appeared on the foreign label. Labels were *not* considered divergent from the medical importance standard simply because information was organized differently, however.

The sources of comparison for screening are listed in table 2-2. For brandname products (or their components) available in the United States (or products with the same active ingredients), the *Physicians' Desk Reference* (PDR) (151) or the *Physicians' Desk Reference for Nonprescription Drugs (152) was* used as the reference. These annual volumes contain the complete FDA-approved labeling for most products sold in the United States; however, it is not mandatory that all products be included in the PDR volumes. One or a combination of other sources were used for products not included in the PDR, either because they are not sold in the United States or because entries for them did not appear in the PDR.

The screening summaries for each product were distributed to the Expert Review Group, along with the actual label (or translation) and a notation of the source used for the screen (less readily available sources, e.g., specific journal articles, were enclosed for the convenience of the members).

The Expert Review Group: First Review

The Expert Review Group consisted of academic and practicing physicians and pharmacologists and one physician consumer advocate (members are listed in the front of this report). All were highly qualified technically to make medical judgments on pharmaceutical information. It was OTA's intention to include technically qualified industry representatives in the group as well, but for legal reasons, this proved problematic for industry, so they chose not to be represented. The members listed all attended at least one meeting; about eight were present at each meeting.

Three 2-day meetings were held between 1988 and 1990 to review the sample labels. About 50

Table 2-2—References Used for Comparison With Sample Labeling

Source	Use in sample
Physicians' Desk Reference **(151)**	**Prescription drugs sold in the United States**
Physicians' Desk Reference for Nonprescription Drugs (152)	**OTC products sold in the United States**
Martingale: The Extra Pharmacopoeia **(184)**	**Drugs that are not approved for sale in the United States**
USP DI **(U.S. Pharmacopeial Convention) (247)**	**Commonly used generic products lacking full prescribing information in PDR.**
American Hospital Formulary Service **(8)**	**Generic products and products not available in the United States**
Goodman and Gilman's The Pharmacological Basis of Threrapeutics (75)	**Basic pharmacologic information.**
Search of medical literature	**Products with no other source of reference.**

SOURCE: Office of Technology Assessment, 1993.

products were reviewed each day. OTA's screening summaries were used as a guide, but discussion was not limited to the points mentioned in them, and the sources of comparison used by OTA were not considered "gold standards." Other references, from standard pharmacology textbooks (75) to specific journal articles, were referred to regularly during these meetings.

The standard of evaluation was "medical importance." The question OTA posed to the group was:

> Is the information provided on this label accurate and is it sufficient to allow a physician to use the product safely and effectively, given what we know about the drug from U.S. labeling and other sources?

The result was a focus on essential medical information, rather than a laundry list of all the "differences" between the foreign labels and either the U.S.-approved label or another comparison. In addition, each medically important deviation was given a relative importance ranking, which eventually was translated by OTA into a numerical ranking.

When the FDA-approved labeling was the screening source, there was general agreement that the *indications* listed were probably well supported, given FDA's strict standards of evidence. However, lack of an indication on the FDA-approved label was not taken as sufficient evidence that an additional indication on the sample label was inappropriate. Other references were often consulted to determine the evidence for and medical acceptability of "unlabeled indications" (see discussion in ch. 4). Most commonly used were the *USP DI (247),* AMA's *Drug Evaluations (7),* and *Drug Facts and Comparisons (46),* each of which routinely lists both labeled and unlabeled indications that are accepted by medical experts in the United States. Expert Review Group members were the final arbiters.

It was recognized by the Review Group and OTA that FDA-approved labeling contains a large number of warnings and precautions that represent rare cases, and may be of limited medical importance. When these were absent from foreign labels, they were not necessarily considered violations of the medical importance standard. Important divergences in warnings and precautions were identified only when the Review Group believed that their absence would hinder a physician's safe and effective use of the product, and might place a patient at undue risk.

After products were reviewed, each instance of a divergence from the medical importance standard, as determined jointly by the Expert Review Group and OTA staff, was formulated into a query to the manufacturer.

Queries to Companies

A summary query sheet was prepared for each product evaluated. If there were no divergences from the medical importance standard, a sheet was still prepared conveying that information, but not requiring a response. For the labels with divergences, queries were organized by category of labeling information. Companies were asked to provide justification or medical evidence to support the adequacy of the labeling as it existed, in relation to each query. The type of information to be submitted was left to the discretion of the companies.

It had been explained in correspondence with the companies that, except for issues requiring clarification, the request for information on the queries would not be reopened, so their responses should be as complete as possible. (OTA was to recant on this and allow further submissions late in the process. This is discussed later in this chapter.)

OTA Evaluation of Company Responses

Companies responded with varying degrees of completeness and with different types of infor-

mation (the types of responses received are described in table 2-3). The responses fell into two broad groupings: "evidence" and "explanations." Although some type of response was given for most queries, one company chose to respond to queries for only a "sample" of their products. Another company sent a list of general responses, and answered the queries with a numbered list of the general responses that applied in each case.

OTA evaluated each response using the criteria given in table 2-3. If the response provided sufficient justification for the existing labeling, or if the company indicated that a revised label had already been prepared that covered the point raised by OTA, the query was considered satisfied. (At the time of the first review for each product, OTA did not require documentary evidence that a revised label had been submitted to the foreign regulatory authority, but this was required later in the process, as discussed below.)

Many of the queries had referred to indications not appearing in the major references used by OTA, and which were considered inappropriate or questionable by the Expert Review Group. The issue in some cases was that the indications were overly broad or vague and might lead to inappropriate use of the product. In general, OTA required evidence from at least one adequately controlled, well-designed clinical trial as support for these additional indications. Submission of articles (or abstracts during the initial round of information seeking) or citations to articles describing the clinical trials were necessary for OTA to evaluate the studies and judge their acceptability as evidence. In some cases, however, companies stated that they had an application pending with the FDA to include the questioned indication on the U.S. labeling. OTA accepted those statements as adequate, as companies were deemed unlikely to go through the long and expensive application process without having carried out the necessary studies. Some of those applications would undoubtedly be approved, and some might be denied. OTA gave the benefit of the doubt to the companies that they did have evidence, and did not attempt to review submissions to FDA.

In many instances, companies stated that the questioned labeling had already been changed or that the changes were pending approval by the foreign drug authority. In some cases, companies

Table 2-3-Categories of Company Responses to OTA Queries

Explanations
- Product is no longer sold by this manufacturer.
- Other manufacturers have similar labeling for this product.
- OTA has misinterpreted information on the label.
- Inclusion of the requested information will be misleading or confusing to patients or practitioners.
- The local regulatory agency will not allow the requested information to be included on the label.
- This information is presented in datasheets that are distributed separate from the product, is included in a drug manual or prescribing guide, or is sent to physicians who request it.
- The information omitted is common medical knowledge.
- The questioned information appears in the label.
- OTA has not correctly translated the label or insert.
- The company will make or consider making the requested changes.
- The local regulatory agency has approved the labeling.
- The labeling complies with local practice customs.
- Regulatory agencies from sophisticated countries have approved the questioned labeling.
- The requested information has been approved for labeling for the same or a similar product marketed in the United States.
- The requested changes are pending with the local regulatory agency.
- The requested information is included in the current product insert (which supersedes the one reviewed by OTA).
- The requested changes are unnecessary for reasons other than noted above.

Evidence
- The questioned indication or lack of warning/adverse reaction/contraindication/precaution is supported by the data.
- The company cited U.S. FDA application materials for this indication.
- The company submitted results from controlled clinical trials as support for an indication.
- The company claimed that certain labeling was supported by studies in uncited literature.
- The company cited anecdotal evidence as support for an indication.
- The company provided support for indications with opinions of medical experts.
- The company provided abstracts of relevant studies as evidence.
- The company provided support with in vivo and in vitro experiments in animal models.
- The foreign labeling includes "unlabeled" indications that are widely accepted in the U.S. but the manufacturer has not obtained formal FDA approval.

SOURCE: Office of Technology Asssessment, 1993.

enclosed the revised labeling, but in many cases, they did not. If the changes had been made or were in process at the time the Expert Review Group had evaluated the particular product, OTA accepted these statements as sufficient evidence to dismiss the query, even if documentation was not included. Documentation for these instances was later sought, however (see below, *Provision of Scoring Sheets to Companies).*

OTA Scoring of Labels

After all company submissions had been evaluated, those queries that had been justified by data or explanations were eliminated from further consideration. The remaining unsatisfied queries formed the basis for calculating a "score" for each product. The scoring system was three-tiered: first, each individual unresolved query was assigned a score based on its seriousness; second, each information category was assigned a score; and third, an overall score for the product was calculated. All aspects of scoring are discussed here and shown in table 2-4.

Table 2-4-Scoring OTA Survey Drugs

Category scores (derived from scores for Individual queries)

score code	Definition
N/A	Not applicable (drug excluded from consideration)
—	No queries in category
0	All queries in category resolved
1	At least one query rated 1; no query rated 2
2	At least one query rated 2
R	Score of R (or 1) in "INGREDIENT' category specifically for failure to list inactive ingredients

Overall scores (derived from category scores)

score code	Definition
N/A	Not applicable (drug excluded from consideration)
0	No queries or all queries resolved
O/R	INGREDIENT Score = R; all other category scores = O
1	Score of 1 in one or more category; no category with score of 2
2	Score of 2 in one category only
3	Score of 2 in two or more categories

SOURCE: Offices of Technology Assessment, 1993.

Individual queries were assigned scores of "l" or "2," representing lesser or greater divergence from the medical importance standard. A score of 2 was generally defined as one for which there was:

> a substantial likelihood that a practitioner relying on the information would use the drug in a manner that could result in nontrivial harm to a substantial proportion of users or severe harm or death to some users.

All unsatisfied queries not fulfilling the criteria for a score of 2 were assigned a score of 1. Overall scores were calculated byexamining the individual query scores *by category of labeling information.*

For clarity, it should be noted that more than one divergence from the standard in a single category (e.g., two medically important adverse reactions missing) did not carry more weight than would one divergence in that category. This allowed OTA somewhat more freedom in stating the queries in the most concise manner. In some cases, similar divergences were grouped together within a category to avoid repeating the same phrase for each one. Whether these would be considered one or several divergences in the scoring was not important because scoring took into account the entire category, rather than the individual queries within each category.

PROVISION OF SCORING SHEETS TO COMPANIES

OTA sent each company the score sheets for their own products. These sheets included all the original queries, with a summary of OTA's evaluation of the evidence that had been submitted on each point. Scores for each remaining unsatisfied query and the overall scores were indicated.

OTA had informed the companies originally that there would not be a second opportunity to respond to the queries, and the scoring sheets were being provided for their information only. A number of companies and members of the Advisory Panel urged OTA to consider additional information submitted by the companies; for a

variety of reasons, complete information had not been submitted during the initial rounds.

In the interest of fairness and completeness, OTA invited the companies to submit additional information on the queries still remaining. Companies were asked to limit their submissions to information available at the time of the Expert Review Group meeting at which the particular product labeling was evaluated (e.g., a labeling change that had been made after OTA's initial review would not be accepted to satisfy the query). OTA also took the opportunity to request documentation for certain statements made in the companies' original responses. Table 2-5 lists the items for which documentation was requested, and the type of material that would be accepted.

This request to the companies also allowed OTA to gather information for an analysis recommended by the Advisory Panel and certain companies. There was some concern that OTA's standard (the "medical importance" standard) was an inappropriate one for products shipped to developing countries from developed countries, mainly European countries, other than the United States. The general feeling was that OTA should take into account the fact that labels rated deficient by OTA's standards might well be identical

Table 2-5-Responses for Which Documentation was Requested

Company response	Requested documentation
The company has applied for changes in labeling with the relevant regulatory authority.	Must be accompanied by dated documentary evidence. Official correspondence with the regulatory authority is acceptable.
The questioned information appears in the labeling pending approval.	The pending labeling must be submitted.
More complete labeling superseded the labeling that OTA reviewed.	Must be accompanied by a dated copy of that labeling, The label must be dated before the evaluation date indicated on the product evaluation sheets.
The questioned information appears in the superseding labeling.	The superseding labeling must be submitted.
The questioned information appears in the labeling that OTA reviewed.	Must be accompanied by a copy of the labeling.
A claim that the local regulatory authority has not required certain labeling.	This is sufficient justification for a deficiency if the manufacturer documents that the regulatory authority rejected more appropriate language. If the local regulatory authorities have devised standard package inserts for certain products, documentation must be provided that these standard inserts are mandated by local health authorities.
Particular labeling is approved in the developed country that the product is exported from.	Must be accompanied by the foreign label from that country accompanied by translation if the original is not in English. (OTA evaluation will still be based on the medical importance standard, however.)
Any questioned indications.	OTA will accept indications supported by adequately controlled clinical trials (excepting only a disease with a well known natural history, where there is evidence that a therapy consistently alters the natural history of that disease).

NOTE: If documentation was not provided, OTA relied on the label reviewed originally. OTA requested that copies of all studies cited for support be submitted, non-English studies translated into English, FDA submissions cited for support provided in summary form, and unpublished data include a clear statement of the study design and a summary of the findings.

SOURCE: Office of Technology Assessment, 1993.

to the approved labels in the developed countries of export.

It was agreed that a subsidiary analysis would be carried out on this point. OTA, therefore, asked companies to submit the approved labeling from the exporting countries for products in the sample. (In the end, this analysis was not carried out because companies did not submit the material, though one did a different subsidiary analysis, which is discussed in ch. 3.)

The new material submitted by the companies was evaluated using the same standards described earlier, and scores adjusted as appropriate. It *was only possible for scores to improve based on new information, except in cases where companies failed to document previous statements.*

Review of OTA Scoring by Expert Review Group

OTA did not routinely seek the advice of the Expert Review Group in evaluating evidence submitted by the companies. In most cases, the evidence either clearly did or did not respond adequately to the queries. The experts were consulted on an ad hoc basis, according to OTA's needs. Initially, therefore, they did not review OTA's scoring.

At the urging of the companies and members of the Advisory Panel, a subgroup of the Expert Review Group met to review the criteria for scoring and the scores themselves, based on the first submissions of the companies. The four members of the Expert Review Group who also served on the Advisory Panel constituted the subgroup, and they were joined by the Advisory Panel chairman, who had not been present at previous Expert Review Group meetings.

In nearly all cases, the Subgroup affirmed OTA's judgments. However, they believed OTA to have been lenient in its judgments, giving the benefit of the doubt to the companies in many more cases than they themselves were willing to do. Consequently, they recommended some changes in the original scoring. The changes were due to the Subgroup rating the absence of certain types of information (mainly adverse reactions) as more medically serious than had OTA. Of the 66 products to which OTA had given an overall score of 3 (greatest divergence from standard), it was recommended that 3 be considered less serious, lowering the scores to 2. Of the 66 originally scored as 2, they recommended lowering scores for 3 to less serious categories and raising 11 products to 3s. Of the 61 initially rated as 1, they recommended lowering 1 to a less serious category and raising 13 to a more serious one. Of the 39 products OTA rated as O initially, no changes were proposed. (The final figures reported in ch. 3 are different from these because they reflect the company's "additional responses." In the end, 59 products, rather than 74, were rated 3.)

By the time of the Subgroup meeting, OTA had already sent the companies evaluation sheets for their additional responses. In the cases where scores had been raised for individual queries from O (OTA's original evaluation) to 1 or 2 based on the Subgroup evaluation, revised evaluations were sent to the companies.

Provision of Summary Sheets to Companies for Additional Responses

In November 1991, the updated summary sheets were provided to the companies for their additional responses, which were received over the next several months. A massive amount of information was submitted by the companies overall, responding much more fully to the queries than they had originally. OTA staff analyzed the new information and rescored all the products. As a whole, the scores improved as a result of the additional responses. In a few cases they were worse, mainly because companies had originally stated that labels had been changed, or that applications for changes had been filed with the country regulatory authority, but the company failed to document these claims in the additional re-

sponse period. Table 2-6 shows the distribution of interim and revised overall scores.

Analysis of Final Results

The results of the evaluation process are presented in chapter 3. All discussion and presentation of scores, both for individual points and products overall refer to the final evaluations, after the material submitted by the companies during both rounds of review had been evaluated and queries were either resolved or not.

Table 2-6—Distribution of Interim and Final Scores

Overall score	Interim score count	Final score count
0	59	78
1	61	42
2	59	63
3	63	59
Not evaluated	31	31
Total	273	273

NOTE: Interim versus final scares were not cross tabulated, so this table cannot be used to determine how many scores changed during the process.

SOURCE: Office of Technology Assessment, 1993.