| Script - An Introduction to the Improved FDA Prescription Drug Labeling |
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| Welcome and thank you for participating in the Food and Drug Administration, Center for Drug Evaluation and Research continuing education activity on the improved prescription drug labeling.<br><br>This activity is designed to give you a better understanding of:<br><br>• the revised prescription drug labeling,<br>• the format changes that were made, and<br>• why they were necessary.<br><br>We'll also discuss other labeling initiatives that are helping FDA fulfill its mission of promoting and protecting the health of the American people in the 21st century. |
| Let me first introduce myself and my colleague who is presenting with me today. I am Mary Kremzner, a pharmacist in the Center for Drug Evaluation and Research Division of Drug Information. And I am Steven Osborne, Medical Officer in the FDA Center for Drug Evaluation and Research.<br><br>The goal of today's program is to make information about the revised prescription drug labeling clearer and more easily understood. For teaching purposes, we're going to be using three fictitious drugs in this activity to describe the nature of the labeling changes. |
| Upon completion of this presentation, you will be able to fulfill the learning objectives of this activity. In short, you should be able to describe the following:<br><br>• The prescription drug labeling and related FDA requirements<br>• The history of the prescription drug labeling initiative<br>• The staged implementation schedule for the revised prescription drug labeling<br>• The major content and format changes to the prescription drug labeling and the rationale for the changes<br>• Other related FDA electronic labeling initiatives<br><br>We have a lot to cover, so let's get started. |
| Let's begin by *generally* defining the term "labeling" and *specifically* describing what prescription drug labeling is. |

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The term "labeling" is *generally* defined by section 321(m) of the U.S. Code as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article."

For this activity, prescription drug labeling will *specifically* refer to the printed information that accompanies prescription drugs (that is, the folded paper inside the carton). The primary purpose of prescription drug labeling is to give healthcare professionals the information they need to prescribe drugs appropriately.

Prescription drug labeling is commonly called by other names such as:

- Prescribing information
- Package insert
- Professional labeling
- Direction circular
- Package circular

Next, we see that prescription drug labeling, as defined in the Federal Regulations, specifically, 21 CFR 201.56, has the following requirements. It must:

- Contain a summary of essential scientific information for the safe and effective use of the drug
- Be informative and accurate
- Use language that is not promotional in tone, false, or misleading
- Not make claims or suggest uses for drugs when there is not sufficient evidence of safety and a substantial evidence of effectiveness
- Contain information based whenever possible on data derived from human experience

The labeling must also be updated when new information becomes available that causes it to become inaccurate, false, or misleading.

**Test Your Knowledge**

True or False: The primary purpose of prescription drug labeling is to give patients information they need to take medications properly.

Answer: False. Although patients may obtain useful information from prescription drug labeling, its primary purpose is to give healthcare professionals the information they need to prescribe drugs appropriately.

Now we will discuss the history of the prescription drug labeling initiative, how the labeling changed over time, and what prompted FDA to make changes to the labeling.

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| Over the years, prescription drug labeling grew in length, detail, and complexity. The older format:<br><br>• did not identify the approval date,<br>• did not indicate whether there were any recent changes to the labeling,<br>• made locating and using information difficult, and<br>• did not facilitate finding answers to specific questions.<br><br>Eventually, in many cases, labeling lost its user focus. It became a document to assure completeness for possible litigation instead of a source of easy-to-use medical information.<br><br>FDA's goal for the prescription drug labeling initiative was to create a more useful risk-safety communication tool and to reduce errors caused by misunderstood or incorrectly applied drug information. FDA focused its effort on making labeling more informative and easy-to-read. |
| In 1992 FDA conducted focus-group research to learn more about the problems with the old labeling. Between 1993 and 1994, the agency conducted a national survey of physicians to gather additional information about how prescribers used labeling and what problems they had with it.<br><br>Prescribers said they use labeling primarily to find a specific item of information or to answer a specific question. They emphasized a number of problems using the labeling and recommended changes to make the labeling easier to use. Prescribers told FDA that they essentially wanted two things. They wanted easy access to certain labeling sections that they found more useful or important. They also said that they would use labeling more often if it included a short (maximum half-page in length) synopsis of the most frequently consulted information. Based on what FDA learned from this research, the agency developed a prototype of proposed labeling and conducted a focus group evaluation.<br><br>In order to implement a new regulation or change an existing one, FDA must obtain public comments and input on proposals. In 1995, FDA held a public meeting to discuss the prototype and received comments to the *Federal Register* notice announcing the meeting. FDA analyzed the comments and over the years worked with the pharmaceutical industry and others to revise the prototype and develop what would become the new labeling. On December 22, 2000, the Proposed Rule for the labeling change was published in the *Federal Register*. Again comments were received and incorporated into the draft. On January 24, 2006, the "Final Rule: Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products" was issued. |

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| You may have heard terms like "Proposed Rule" and "Final Rule," among others. Let's provide some background on these terms so they make sense as we continue. The federal government uses a publication called the *Federal Register* to communicate on a daily basis its decisions and activities. When FDA publishes a Proposed Rule in the *Federal Register*, in essence the agency is asking for public comments from interested parties. Depending on the topic, FDA receives comments from consumers, industry, patient advocacy groups, healthcare professionals, and others. At the end of the comment period, the FDA reviews and analyzes all the comments it received on the Proposed Rule. The Proposed Rule is then modified to address the public comments, and a Final Rule is issued. |
| Once the Final Rule is published in the *Federal Register,* it becomes official and is incorporated or codified into the next edition of the *Code of Federal Regulations*, or CFR. You can see that it takes years to complete a Final Rule. We mentioned earlier in the presentation that developing the new labeling Final Rule took approximately 14 years. Practicing physicians, the pharmaceutical industry, consumers, professional organizations, and others collaborated with FDA to make this possible. Now that you know something about the regulatory process, let's learn more about the focus of this activity, the new prescription drug labeling. |
| You may be wondering what products the rule affects and when this rule will be implemented. The products affected by the rule include applications for prescription drugs and biologics:<br><br>• Submitted to FDA on or after June 30, 2006<br>• Approved by FDA 5 years prior to June 30, 2006<br>• With major changes in the prescribing information approved five years prior to, on, or after June 30, 2006. Major prescribing changes could include approval of a new use, a new dosage regimen, or a new route of administration. |
| **Test Your Knowledge**<br><br>True or False: FDA conducted focus groups, surveys, and public meetings with prescribers to determine how the labeling should be changed.<br><br>Answer: True |
| Now, let's take a look at the implementation schedule for the new labeling requirements. |

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| This table illustrates FDA's phased-in approach for pharmaceutical industry compliance with the new labeling requirements. The schedule bases compliance on the date a new drug application was submitted to the agency. It essentially gives companies whose products were approved many years ago more time to update their labeling. It also ensures that labeling for the newer prescription drugs will be updated first. These are typically products with more complex labeling and products practitioners refer to more often**.** |
| **Test Your Knowledge**<br><br>True or False: Labeling for all prescription drugs must conform to the new format by the year 2010.<br><br>Answer: False. FDA has provided a flexible implementation schedule that phases in the new labeling requirements. The schedule for implementation depends on when the application was approved by the agency. Companies whose products were approved many years ago have more time to update their labeling, while ensuring that new products will be updated first. |
| Let's see how the FDA's labeling rule changes the format and content of drug labeling. |
| We'll begin by providing an overview of the new labeling format.<br><br>The first format change we will discuss is the addition of a section called, "Highlights." This is perhaps the most significant change in the new labeling rule. The Highlights section was created because prescribers said they would use labeling more if it included a short, half-page synopsis. The Highlights section does this. It provides the overview of a drug's benefits and risks that healthcare professionals said was most important to them. The Highlights section will be discussed in greater detail later in this activity.<br><br>Another format feature all prescription drug products will share is the new "Contents" section in the product labeling. This table of contents is an easy-to-use reference to detailed safety and efficacy information. The Contents section addresses prescribers' concern that it was difficult to use the old labeling format to find specific information. The Contents section will be discussed later in the presentation as well.<br><br>We will discuss in further detail how the new labeling reorders and reorganizes sections in the old labeling format. And last, we will discuss other improvements that were made to the labeling, including format requirements and a method to identify recent changes to the labeling. |
| Here is an illustration of the first page of the old product labeling format. |

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| Here you see an illustration of the first page of the revised product labeling format. When the two formats are compared, you will note that the revised labeling offers significant enhancements, including:<br><br>• A Highlights section at the top of the page,<br>• A Contents section to serve as a navigational tool,<br>• Reordered and reorganized frequently referenced sections,<br>• Format changes that make the labeling easier to read, and<br>• Consolidated safety information. |
| The Highlights section guides healthcare professionals to sections in the "Full Prescribing Information" where detailed information about the product can be obtained. Highlights are not a verbatim repetition of selected information from the Full Prescribing Information, or simply a repetition of the Contents. They are a concise summary of crucial prescribing information. Essentially, the Highlights section is a brief one-half page summary of the more descriptive product labeling.<br><br>Highlights sections include:<br>• Limitations Statement<br>• Product Names and Date of Initial U.S. Approval<br>• Boxed Warning<br>• Recent Major Changes<br>• Indications and Usage<br>• Dosage and Administration<br>• Dosage Forms and Strengths<br>• Contraindications<br>• Warnings and Precautions<br>• Adverse Reactions<br>• Drug Interactions<br>• Use in Specific Populations<br>• Patient Counseling Information Statement |
| Here is an example of the Highlights section in the labeling for a fictitious drug called *Imdicon*. As you can see, it is a summary of the labeling and contains the highlights of the Full Prescribing Information in bulleted format. This makes it much easier to find the information you need. Also note the numbers that appear in parentheses. These numbers refer to the appropriate section in the Full Prescribing Information. |
| Now we're going to take a closer look at each section within the Highlights. At the top of each Highlights page, you will see a "Limitations Statement." For example, "These Highlights do not include all the information needed to use *Imdicon* safely and effectively. See Full Prescribing Information for *Imdicon*." This is very important. Although the Highlights are useful for quick information, healthcare professionals need to know that the labeling contains more detailed information than that presented in the Highlights. |

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| The next section is "Product Names and Date of Initial U.S. Approval." This section provides an immediate flag about the relative newness of a product, something healthcare professionals told us was very important to them. Here you will see the name of the drug and the year FDA initially approved it, along with the brand and generic names of the drug. Our example shows that *Imdicon* was first approved by FDA in 2000. |
| Next we see the "Boxed Warning" section. As in the old product labeling, the revised product labeling may contain a boxed warning, also referred to as a black-box warning. The boxed warning in the Highlights section uses bullets for ease of reading and is limited to 20 lines. The complete boxed warning in the Full Prescribing Information may be longer and contain a more thorough explanation of the risks. This Highlights section even tells us to go straight to sections 5.1 and 5.2 of the Full Prescribing Information to find more information about these warnings. |
| Moving on, we see "Recent Major Changes." Looking at the labeling, you may simply want to know whether or not there have been any important updates or changes, rather than reading through the entire document. Here is another place where the Highlights section is very useful. Recent Major Changes lists modifications that have been made to the sections that contain the most critical prescribing information:<br>• Boxed Warning<br>• Indications and Usage<br>• Dosage and Administration<br>• Contraindications<br>• Warnings and Precautions<br><br>So, looking at *Imdicon*, we see that labeling changes have been made and the date the changes were made to two sections, "Indications and Usage" and "Dosage and Administration." We can now go to sections 1.2 and 2.2 of the Full Prescribing Information to view these changes. A margin mark will appear in the corresponding section of the Full Prescribing Information to indicate where the change occurred. |
| The next section is "Indications and Usage." Let's say you want to know exactly what *Imdicon* is approved for so that you can determine whether you need the most detailed information to decide whether this product is appropriate for your patient. The Highlights section lists, in bulleted form, the indications for the drug. It also lists the pharmacological class of the drug so that you are reminded of how the drug works. From this section, we learn that *Imdicon* is a platelet aggregation inhibitor. It is FDA-approved for reducing the risk of thrombotic stroke in patients who have experienced stroke precursors or who have had a completed thrombotic stroke, and for reducing the incidence of subacute coronary stent thrombosis when used with aspirin. In addition, we learn that the indication has limitations and that *Imdicon* should be reserved for patients who are intolerant of, or allergic to, aspirin or who have failed aspirin therapy. |

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| The next two sections, "Dosage and Administration" and "Dosage Forms and Strengths," tell us the recommended dosage regimen for the given indications, along with the starting dose, and the dose range. They also tell us whether to take the drug with or without food, critical differences among population subsets, monitoring recommendations, and significant clinical pharmacologic information. |
| Here, we can tell at a glance the dosage forms for the drug. |
| Moving on, we see the "Contraindications" section. The Contraindications section tells us in a clear, bulleted format, situations in which the drug should absolutely NOT be used. There are no *relative* contraindications. So we can see that anyone who has hematopoietic disorders, a history of TTP or aplastic anemia, hemostatic disorder or active bleeding, or severe hepatic impairment should never take *Imdicon*. |
| The next section is "Warnings and Precautions." The Warnings and Precautions section is an abbreviated summary of the most clinically significant adverse reactions and what to do about them. Additionally, it gives us information about the monitoring parameters for these side effects. |
| The next section is "Adverse Reactions." Whereas the Warnings and Precautions section lists the more serious adverse events that can occur when using the drug, the Adverse Reactions section lists the most commonly occurring adverse reactions, along with the percentage of occurrence. This section contains information on how to report adverse reactions to the manufacturer and to MedWatch, FDA's Adverse Event Reporting System. |
| The clear and concise bulleted "Drug Interactions" section tells us about clinically significant drug interactions and gives us a brief explanation of the nature of the interaction. Additional information also appears in several sections of the Full Prescribing Information. Just a brief glance at the Highlights page for *Imdicon* will tell us that it interacts with anticoagulants and phenytoin, and informs us of the potential outcome of the interaction. |
| Moving along, we see the section titled "Use in Specific Populations." Use in Specific Populations was previously integrated into the Precautions section. This new section gives us a bulleted summary of any important information about use in specific populations, such as in pregnancy, labor and delivery, nursing mothers, pediatric, geriatric, or hepatically or renally impaired patients. Again, we no longer have to look through the entire labeling to find this information. We can glance at the Highlights for *Imdicon* to learn about special dosing in the hepatically and renally impaired, and we know exactly which sections to zoom into in the Full Prescribing Information to learn more about needed prescribing adjustments. |
| The last section of the Highlights page directs us to "Patient Counseling Information" and to the FDA-approved patient labeling. Patient counseling information is written for healthcare professionals to remind them about what information is important to convey to the patient, whereas FDA-approved patient labeling is written for a lay audience. This section will be discussed in greater detail later in the presentation. |

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| **Test Your Knowledge**<br><br>True or False: The Adverse Reactions section within the Highlights contains contact information for reporting suspected adverse reactions.<br><br>Answer: True. The Adverse Reactions section lists the telephone number and Web address for both the manufacturer and MedWatch, FDA's Adverse Event Reporting System. |
| Now that we've discussed the Highlights, let's talk about the other new format addition, the Contents, which is a table of contents to the Full Prescribing Information. |
| As stated earlier in the program, the Contents serve as a navigational tool to all sections and subsections in the Full Prescribing Information and provide electronic hyperlinks to those sections. |
| Here is an example of Contents for a fictitious drug. Note that some of the sections include relevant subsections that will make finding specific information in the labeling much easier. |
| Another major format change in the improved prescription drug labeling is the reordering and reorganizing of sections. The "Indications and Usage" and the "Dosage and Administration" sections (information that healthcare professionals refer to most frequently and consider most important) are located at the beginning of the prescribing information.<br><br>Some product identification information such as color and scoring is located in both the "Dosage Forms and Strengths" and the "How Supplied" sections to preserve the integrity and understanding of both sections.<br><br>Next, the previous Warnings and Precautions sections were consolidated into one section that contains the most critical safety information. Sections previously located in the Precautions section (Drug Interactions, Use in Specific Populations, and Patient Counseling Information) are now new sections in the labeling.<br><br>The "Adverse Reactions" section follows the Warnings and Precautions section and consolidates risk information in one location.<br><br>These changes help put into context the relative seriousness of the adverse reactions discussed.<br><br>Last, the "Clinical Studies" and "Nonclinical Toxicology" sections, which were previously optional, are now required. |
| This chart is an example of where risk information was located in the previous format and where it is located in the revised format. |

**Test Your Knowledge**

Multiple Choice: The most significant format and section reordering changes include:

A) Moving the information practitioners refer to most frequently and consider most important to the bottom of the prescribing information
B) Consolidating risk information
C) Deleting the Storage and Handling section
D) A and B
E) All of the above

Answer: B

Let's talk in more detail about the newly added sections. As mentioned previously, there is a new section titled, "Drug Interactions." Drug interaction information now appears in section 7: "Drug Interactions" and in section 12: "Clinical Pharmacology." Section 7 includes a list of other drugs (or classes of drugs) or foods that interact or are predicted to interact in clinically significant ways with the drug. It also includes practical instructions for preventing or decreasing the likelihood of the interaction. And last, it includes when the drug interaction information rises to the level of a warning, precaution, or contraindication, or necessitates a dosage adjustment. This information is briefly discussed in the applicable section(s) with details in section 7: Drug Interactions.

Section 12: Clinical Pharmacology describes the drug-drug interaction study results and alerts prescribers to the magnitude of a particular interaction.

Another new section is the "Patient Counseling Information." The addition of this new section brings up two important questions. First, why does FDA require FDA-approved patient information to be reprinted in or accompany prescribing information when it also requires the Patient Counseling Information section?

FDA-approved patient information and the Patient Counseling Information section have distinct purposes. Patient Counseling Information is specifically written for healthcare professionals to remind them about what information is important to convey to the patient at the time of prescribing in order for the drug to be used safely and effectively. (FDA studies have shown that it is at the prescribing visit when most patients receive their drug information.)

In contrast, FDA-approved patient information, which includes patient package inserts and medication guides, is specifically written for a lay audience and is intended to be read by patients. It is designed to communicate in understandable language the most important information patients need to use the product appropriately. Under the new regulations, all FDA-approved patient information, including Medication Guides, must accompany or be appended to the prescribing information. In addition, FDA fully expects that those responsible for developing patient information that FDA does not regulate will use the new format, particularly Highlights, as a guide.

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| The second question we need to consider is whether the Patient Counseling Information section is required for medications that are only administered in the hospital setting. The answer is, "Yes." The Patient Counseling Information section must be developed unless it is clearly inapplicable. There is almost always information about a drug that is important for the prescriber to convey to the patient, such as potential adverse drug reactions, even for products that are administered in the hospital by a healthcare professional. |
| Now that we've finished talking about the new sections of the labeling, let's talk about other revisions and improvements. |
| Revisions were made to the safety information sections. Specifically, new changes can be seen in the "Contraindications" section, the "Warnings and Precautions" section, and the "Adverse Reactions" section. |
| Let's talk in more depth about these revised safety sections. We'll start with the Contraindications section. It's important to remember that a contraindication exists only when the risk from use clearly outweighs any possible therapeutic benefit. It should include only known hazards. For example, you will no longer see the statement that usually appears in the Contraindications section, "allergic to any component of the drug." Also, the order in which the contraindications should appear in the labeling is based on the likelihood of occurrence and the size of the population affected. |
| Next is the "Warnings and Precautions" section. Warnings and Precautions have been consolidated into one section. In addition to the consolidation, the section has been expanded to include *clinically significant adverse reactions*. Examples of clinically significant adverse reactions include:<br><br>• Adverse reactions that require discontinuation, dose adjustment, or addition of another drug<br><br>• Adverse reactions that could be prevented or managed with appropriate patient selection or avoidance of concomitant therapy<br><br>• Adverse reactions that significantly affect patient compliance |

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| And last, the "Adverse Reactions" section. The new Adverse Reactions section requires a separate listing of adverse reactions that occurred during clinical trials and those that were reported after the drug was marketed. Adverse reactions from postmarketing clinical trials should be included with the clinical trial experience. Postmarketing spontaneous adverse reaction reports must be listed separately.<br><br>The Adverse Reaction section will no longer contain the extraneous events or laundry lists of adverse reactions. Rather, it will supplement with additional detail, the nature, severity, frequency of adverse reactions, and the relationship to dose and demographics. |
| Other improvements in the labeling are format requirements. These include using a minimum 8-point font size to improve readability and using multiple formats, such as tables and bullets, and bolding and white space to help improve visual and cognitive access to the drug information.<br><br>The new labeling encourages adverse reaction reporting and provides contact information, both a toll-free number and an internet address, for reporting serious and non-serious adverse reactions. |
| **Test Your Knowledge**<br><br>Multiple Choice: What changes did FDA make to the prescription drug labeling to better communicate to healthcare professionals?<br><br>A) Added the Highlights section which effectively organizes and chunks information into logical groups to enhance accessibility and retention<br>B) Used graphic emphasis, such as standardized bolding and white space, to improve visual and cognitive access to information<br>C) Limited the amount of text in the Dosage section<br>D) A and B<br>E) All of the above<br><br>Answer: D |
| We have spent quite some time describing the major content and format changes to the prescription drug labeling, including why FDA made the changes. Next, we focus on some other questions about the new labeling. |

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| The first question is, "Where do I find microbiology data?" As you can see for the fictitious drug *Friendchip*, a dental antimicrobial, there is a specific subsection in the Clinical Pharmacology section (i.e., 12.4 Microbiology). All microbiology information for antimicrobial products, such as *Friendchip,* is consolidated in this section. |
| Another question is, "Why is some information in more than one section of the new labeling?"<br><br>It's important and appropriate to repeat some information in more than one section, based on the type of information and the clinical relevance. The information is repeated in varying levels of detail in different sections. Generally, you will find that one section contains the detail; other sections contain a brief description with a cross-reference. We'll use drug interaction information to illustrate cross-referencing. |
| Drug interaction information may need to be included in several sections in varying levels of detail, such as when a drug is co-administered with another drug and a serious adverse reaction occurs. You would find details about the interaction in the Drug Interactions section. You would also find brief interaction information in other sections of the labeling such as in the Contraindications or Warnings and Precautions sections. You might even find a Boxed Warning that covers the most important interaction information. These brief discussions always include a cross-reference to the detailed information in the Drug Interactions section. If a dose adjustment is needed, the Dosage and Administration section would include information about the drug interaction and how to adjust the dose. You may recall that you will find any details about drug interaction studies in the Clinical Pharmacology section. |
| What if you wanted to know about dose adjustments? Where would you find dose adjustment information? You will find dose adjustments in two sections of the labeling.<br><br>Section 2, the Dosage and Administration section, includes instructions for recommended dose regimen and dose adjustments for the drug.<br><br>Section 7, the Drug Interactions section, may include instructions for dose adjustments for concomitant medications. |
| Let's look at an example for another fictitious drug, *Hivavir*. As you can see from the chart, *Hivavir* increases the concentrations of another drug *Sinubact* by 50%. In the Drug Interactions section of the labeling, you would find information about a recommended reduction in the *Sinubact* dose. At the same time, you can see the Dosage and Administration section of the labeling notes that *Hivavir* interacts with *Waramine,* and requires an increased dose recommendation for *Hivavir*. |

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| To help put the information presented up to this point into practice, the following case study is presented. Please note the drug names used in the case study are fictitious.<br><br>*LV is a 68-year-old black male making a routine visit to his physician. LV's medical history includes depression and AIDS since April 23, 1999. LV is currently taking Hivavir 1000mg once daily, Aidsudine 30mg twice daily, and Deprexetine 20mg at bedtime. LV reports no recent drug or alcohol use and has very good self-reported adherence with his antiretroviral therapy. LV's recent lab results showed his Hivavir concentration was suboptimal.* |
| A possible drug-food interaction and/or a drug-drug interaction involving *Hivavir* could explain why LV's *Hivavir* concentration was suboptimal.<br><br>Question: Which section of the labeling should LV's healthcare professional reference?<br><br>Answer: Drug-drug interactions and drug-food interactions can be found in Section 7: Drug Interactions. Other sections to reference include:<br><br>▪ Section 5: Warnings and Precautions for monitoring issues and adverse reactions that require dose adjustment or avoidance of concomitant therapy<br><br>▪ Section 2: Dosage and Administration for potential dose adjustments<br><br>▪ Section 12: Clinical Pharmacology for pharmacokinetics |
| After *Hivavir* was marketed, FDA began receiving reports of life-threatening hematological reactions. As a result, the labeling was revised.<br><br>Question: Which section(s) of the Highlights should LV's healthcare professional reference to learn more?<br><br>Answer: LV's healthcare professional should first reference the Boxed Warning and Warnings and Precautions. Other sections to look at include Recent Major Changes, which would note which sections were revised and when. |
| The final learning objective for this activity is to describe other related FDA electronic labeling projects. The new prescription drug labeling format will be integrated into FDA's other electronic health initiatives and standards-setting efforts. |

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| For example, in November 2005, the FDA began requiring drug manufacturers to submit prescription drug labeling information in the Health Level Seven XML-based structured product labeling format. Structured product labeling provides accurate, up-to-date drug information using standardized medical terminology and a readable, accessible format. Health Level Seven is a standards developing organization operating in the healthcare arena.<br><br>With embedded computer tags, information in the structured product labeling format can be electronically managed, allowing a user to search for specific information. These tags can instruct computers to read specific sections of a prescription drug labeling including product names, indications, dosage and administration, warnings, description of drug product, active and inactive ingredients, and how the drug is supplied.<br><br>Prescription drug labeling submitted to FDA in the structured product labeling format will help support initiatives to improve patient care by using electronic prescribing to manage healthcare information better.<br><br>The revised format is important to the success of other initiatives, such as DailyMed, that are aimed at improving patient care and decreasing the likelihood of medication errors based on misunderstood or incorrectly applied drug information. |
| FDA makes structured product labeling available to healthcare information providers on its Facts@FDA Web site. Facts@FDA can be accessed from the main FDA Web site at www.fda.gov. The Web site provides up-to-date labeling information on FDA-regulated products. You can download a single ZIP file for the content of labeling for approved prescription drugs. The Web site is being updated with structured product labeling as it is submitted to FDA. |
| DailyMed, a drug labeling Web site created by FDA and the National Library of Medicine, has begun to electronically disseminate up-to-date and comprehensive medication information for use with information systems that support patient care. DailyMed will make current labeling information about FDA-regulated products readily available, free of charge, to physicians, other healthcare professionals, and patients. This is an important step toward creating electronic access to drug safety and effectiveness information at the point of care. |

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| A lot of information has been presented to you today. Next, please notice the link to information available on FDA's Web site about improved prescription drug labeling. FDA's Web site lists additional resources to help facilitate the implementation of the new prescribing information requirements. You will also find information on FDA guidance documents that provide detailed instructions for manufacturers on how information should be presented in different sections of the labeling.<br><br>FDA has developed several prototypes of prescribing information that illustrate approaches to complying with the content and format requirements. We've used sections of *Imdicon, Friendchip*, and *Hivavir* as examples in this session. The complete prototypes and other examples are available through the Web site listed here.<br><br>In the Information for Healthcare Professionals section, you will find a summary of the new requirements and a downloadable brochure. |
| This concludes our activity. We hope you now have a better understanding of the FDA revised prescription drug labeling, and of the format changes that were made and why they were necessary. We are excited about the new labeling initiative and the advances in electronic labeling and hope to share more information about these in the near future.<br><br>We hope you enjoyed today's continuing education session. If you have questions or would like more information on prescription drug labeling, please call us at 888-INFO-FDA or send an email to Druginfo@fda.hhs.gov. At this time, to receive continuing education credits, please complete the online evaluation survey and post-test. Thank you. |