

#	More Technical Word/phrase	Example of word/phrase in a sentence	Plain language alternative	Example using plain language
1	concomitant	Healthcare professionals should advise consumers and patients about the appropriate concomitant use of ibuprofen and aspirin.	“combined use”	Healthcare professionals should advise consumers and patients about the appropriate combined use of ibuprofen and aspirin.
2	contraindicated	This medicine is not recommended in patients with moderate cirrhosis (liver disease) and contraindicated in patients with severe cirrhosis.	“should not be used”	This medicine is not recommended in patients with moderate cirrhosis (liver disease) and should not be used in patients with severe cirrhosis.
3	indicated	The drug is indicated for chronic weight management in patients who are at least 50 pounds overweight or have a weight-related condition such as diabetes or high blood pressure.	“approved to treat”	The drug is approved to treat chronic weight management in patients who are at least 50 pounds overweight or have a weight-related condition such as diabetes or high blood pressure.
4	endpoint	Most [participants OR subjects] ¹ treated with this medicine in the clinical trial achieved normal blood pressure levels, which was the primary study endpoint.	“outcome measured in the study”	Most [participants OR subjects] treated with this medicine in the clinical trial achieved normal blood pressure levels, which was the primary outcome measured in the study.
5	compounded drug	Compounded drugs pose unique risks because they are not	“drugs with combined, mixed, or altered ingredients to	Drugs with combined, mixed, or altered ingredients to create

¹ Seven interviewees should see the endpoint version using “participants,” 8 should see the endpoint version using “subjects,” 8 should see the outcome version using “participants,” and 7 should see the outcome version using “subjects.”

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		reviewed by the agency for safety, effectiveness, or quality before they are provided for patient use.	create a medication tailored to the needs of an individual patient”	a medication tailored to the needs of an individual patient pose unique risks because they are not reviewed by the agency for safety, effectiveness, or quality before they are provided for patient use.
6	postmarket	The FDA is strengthening the requirements for drug companies to generate postmarket data on the long-term impact of the use of opioid pain medicines.	“after a drug is FDA-approved and being prescribed to patients”	The FDA is strengthening the requirements for drug companies to generate data on the long-term impact of the use of opioid pain medicines after they are FDA-approved and being prescribed to patients.
7	adverse events	Adverse events such as heart rhythm problems can occur when taking this medicine.	“harmful side effects”	Harmful side effects such as heart rhythm problems can occur when taking this medicine.
8	efficacy	The study’s major efficacy outcome measure for the drug was cancer tumor shrinkage.	“how well the drug worked”	The study’s major outcome measure was to see how well the drug worked to shrink cancer tumors.
9	bioequivalent	The manufacturer of a generic drug must demonstrate that it is bioequivalent to the brand name drug.	“produces the same effect when treating a condition”	The manufacturer of a generic drug must demonstrate that it produces the same effect as the brand name drug when treating a condition.
10	firms	Over the past several years, FDA has issued several warning letters to firms that	“drug manufacturers”	Over the past several years, FDA has issued several warning letters to drug

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		market unapproved new drugs that contain a substance called cannabidiol or CBD.		manufacturers that market unapproved new drugs that contain a substance called cannabidiol or CBD.
11	misbranded	The products cited in the warning and online advisory letters posted today are unapproved new drugs or misbranded drugs	“improperly labeled”	The products cited in the warning and online advisory letters posted today are unapproved new drugs or improperly labeled drugs
12	pharmacogenomics	The public workshop explored how FDA, the drug industry, and external scientists can work together to advance pharmacogenomics.	“research on how people’s genes affect how they respond to medications”	The public workshop explored how FDA, the drug industry, and external scientists can work together to advance research on how people’s genes affect how they respond to medications.
13	new molecular entity	This is the first new drug application for a new molecular entity approved under a new pilot program called the Real-Time Oncology Review.	“novel new drug”	This is the first new drug application for a novel new drug approved under a new pilot program called the Real-Time Oncology Review.
14	adulterated	The FDA remains fully committed to aggressively pursuing those who distribute adulterated drugs and place unsuspecting American consumers at risk.	“tampered with”	The FDA remains fully committed to aggressively pursuing those who distribute drugs that have been tampered with and place unsuspecting American consumers at risk.
15	liver decompensation	Liver decompensation is the major cause of death in patients with	“decreased liver function”	Decreased liver function is the major cause of death in

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		hepatitis C who have liver cirrhosis.		patients with hepatitis C who have liver cirrhosis.
16	labeling	FDA is requiring a new warning to describe the serious mental health side effects to be added to the labeling of this allergy medicine.	“prescribing information”	FDA is requiring a new warning to describe the serious mental health side effects to be added to the prescribing information of this allergy medicine.
17	methodological limitations	All of the available studies have methodological limitations.	“limitations in how the studies were designed and carried out and in the data available for analysis”	All of the available studies have limitations in how they were designed and carried out and in the data available for analysis.
18	not statistically significant	These side effects were uncommon in all the study participants, and the increased risk for those who received the medicine was not statistically significant.	“uncertain whether the excess risk for the DRUG group was due to the drug or due to chance”	These side effects were uncommon in all the study participants, and it was uncertain whether the increased risk for those who received the medicine was due to it or to chance.
19	post-marketing clinical trials	FDA may require post-marketing clinical trials for a drug to gather additional safety and efficacy data.	“clinical trials conducted after the drug is FDA-approved”	FDA may require clinical trials be conducted after the drug is FDA-approved to gather additional safety and efficacy data.
20	Risk Evaluation Mitigation Strategy (REMS)	FDA is requiring new restrictions to the prescribing and use of this medicine because of an increased risk of heart attacks in patients treated with it. The new restrictions are part	“a drug safety program that the FDA can require for certain medicines with serious safety concerns to help ensure the benefits outweigh thier risks.”	FDA is requiring new restrictions to the prescribing and use of this medicine because of an increased risk of heart attacks in patients treated with it. The new restrictions are part

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		of a Risk Evaluation Mitigation Strategy (REMS).		of a drug safety program FDA can require for certain medicines with serious safety concerns to help ensure their benefits outweigh their risks.