

USER GUIDE

HOMEPAGE



Pharmasift maintains its simple and clean design along with the powerful sifting algorithm. Whatever you can do on your desktop computer, you can do on your mobile device.

TIP: Holding your mobile device in landscape will switch the site design to look similar to that of desktop.

Pharmasift was designed to be the most comprehensive collection of OPDP enforcement action letters on the market.

In addition to being searchable, it is fast, intuitive, and optimized for mobile devices.

Try it!

Simply type in **www.pharmasift.com** on your mobile device and take this important resource to your review committee meetings.



SIGN UP

Click **SIGN UP** in the top navigation and fill in the empty fields.

Someone from Pharmasift will contact you within 24 hours to schedule a demo.

If your company has a subscription for Pharmasift, your account will be activated within 24 hours with full access to the site.



LOGIN

Once your company has a subscription for Pharmasift, click Login in the top navigation and fill in the empty fields.

Once you click **LOGIN**, you will have full access to the site.

SIFTING

Pharmasift	Sif	Logout	About
			SIFT

Pharmasift isn't your out of the box sift tool. It was designed for regulatory professionals by regulatory professionals.

The powerful sifting algorithm was developed completely in house from scratch. Although the logic behind the sift is proprietary, let's review some information about sifting that might help you optimize your results.

SIFTING - TYPES OF SIFT

WORD SIFT

Type in individual words and the site will sift through every enforcement action letter for that specific word. For example: Twitter

PHRASE SIFT

Type in a phrase WITH quotes and the site will sift through every enforcement action letter for that specific phrase. For example: "Mechanism of Action"

COMPLEX SIFT

Type in a phrase WITHOUT quotes and the site will sift through every enforcement action letter and display results that contain ALL words in the Sift field, regardless of the order each word appears in the letter. For example: patient preference claim in brochure

PHRASE vs. COMPLEX SIFT

Type in a phrase WITH quotes and the site will sift through every enforcement action letter for that specific phrase.

E Pharmasift			Sif	t Logout	About
"OMISSIO	N OF	RISK"			SIFT
VIEW ALL					
E Pharmasift		Sift Logou	t About		
NEW SIFT "OMISSION OF RISK" 14	19 matches			Sift Logout	About
2016 2016 PRECEDEX UNTITLED LETTER	2016 PRE	Pharmasift2016 PRECEDEX UNTITLED LETT			×
2016 ULESFIA WARNING LETTER	Product Name Precedex	Company Name Hospira	Type of Enforcement Action Untitled Letter	Date of Violation January 14, 2016	
2015 ESTROGEL UNTITLED LETTER	Type of Violation Omission of Risk Info Omission of Material Failure to Submit Uno	Type of Violation VIEW Omission of Risk Information VIEW Omission of Material Fact Failure to Submit Under Form FDA-2253 VIEW #		MENT LETTER	
2013 HERIDGING ONTITEDLETTER	Keyword Sift OMISSION OF RISK OMISSION OF RISK Infor Metatag: OMISSION OF F	mation: Promotional materials are IISK Information.			

PHRASE vs. COMPLEX SIFT

Type in a phrase WITHOUT quotes and the site will sift through every enforcement action letter and display results that contain ALL words in the Sift field, regardless of the order each word appears in the letter.



SIFTING - KEYWORD SIFT

Keyword Sift at the bottom of the result page highlights the single word, phrase, or multiple words that are found in the enforcement action letter. This can be extremely useful when determining whether the enforcement action letter is the one you are looking for.

OMISSION	of Risk Information: Promotional materials are	
OMISSION	of Material Fact: The video makes	
Metatag: OI	MISSION of Material Fact.	
Metatag: OI	MISSION of Risk Information.	
RISK		
1 The video	is false or misleading because it omits RISKs and material facts associated with Precedex.	
indication	and summary of the most serious and most common RISKs associated with the use of Precedex.	
and second d	per pet recorracily concernent the DISK information that should be included in the	

SIFTING - OPTIMIZING RESULTS

Pharmasift is not only powerful but simple.

We covered all the bases. When sifting without quotes, Pharmasift will ignore some common words that may appear in most letters, like "the" "of" "in" etc.

Pharmasift also ignores most two letter words.

Don't worry, Pharmasift will appropriately sift important two letter words like "ad" or "tv".

Keep your sift simple.

Let Pharmasift do all the heavy lifting. Pharmasift will automatically sift the word with 40 of the most common prefixes and suffixes.

For example, sifting for "investigation" will also display results for "investigational.

Leave out symbols.

Pharmasift prefers sifting without additional symbols like - + # @ . If you do use symbols, try again without them.

Fully metatagged.

All records contain additional metatags.

For example, a sift for "website" will also show results containing the word "webpage" or "online" even if the enforcement action letter only contains "webpage" or "online" and not "website".

SIFTING WALKTHROUGH

SIFT PAGE



- SIFT: Sift through all enforcement action letters to find only those containing the word(s) in the field.
- 2 VIEW ALL: View all enforcement action letters without sifting.

RESULTS PAGE



- 3 RESULTS: First sorted by year. Then sorted by untitled letter or warning letter. Always in alphabetical order.
- OMITTED WORDS: Pharmasift will ignore certain words.
- 5 First 5 years are expanded. Remaining years are in a collapsed bar

DETAIL PAGE



- OVEW: Opens up a searchable PDF of the enforcement letter or promotional material.
- 7 TYPES OF VIOLATIONS: List of all violations identified by OPDP.
- 8 KEYWORD SIFT: Preview of how the word or phrase appears in the enforcement letter.