

Kill Oil

(AB) No legal requirement
Why an issue?

(JB) Almost a non issue.

More proprietary rights to an ingredient.

(AB) Does need to comply?

(JB)

(AB) Yes it is kill oil - safety given new CG
Who cares?

(SM) Camp g becoming mandatory

Can enforce a camp guideline

(JB) Condition of listing - within into definition of ingredient

(SM) Can camp guidelines be part of ingredient rule.

Not mention list of contaminants.

(JB) Can add leaf

Requirement of listing, not camp guidelines

(JB) Requirement of ingredient.

(AB) Do have capacity to review efficacy.

(AB) Dosage

Look at dosage and efficacy of medicine.

Evidence to support use.

Questions about therapeutic use, promise pick up in
Post Market.

Cannot look at efficacy of new listable substance.

Has to be met

Sign off on active ingredients.

RG Camp guidelines not mandatory.

Work around

No docs to describe.

Something in place

Likely to arise.

Any sponsor can put any kill oil
have an own guideline.

Differ sponsors can use differ kill oils

Not issue

① Need legal underpinning $\rightarrow$ claim

② Commercial - exclusivity of substance
- Use art

Is exclusivity something that should be considered

(MJS) Train out of control

Are they delivering what we need?

Legislate or find alternative

(RO) Task - original compositional guidance

(LB) Essentially same, different paradigms.

How are they created?

(AB) Concerning

(BW) Specification criteria

- Peroxide 10 to 12 lessening of

peroxide - 1.6 to 2

transfer .1 to .2

not nearly nice or clean.

By increasing criteria, compromising safety.

1st product higher quality

(SB) Refer further, quality declined $\rightarrow$ different substances.

Quality hasn't changed

Matter of safety

(RO) less than allowed in fish oil

From a safety aspect, non-issue.

Markets were evaluated for safety

(HM) New substances - evaluated and added

Description

(HW) Sponsor B, same but different - is it sufficiently similar

(RO) Don't submit to TGA

(JB) Can't know if they know or us know.

(RO) Market and shot up.

(HW) Significant differences e.g. fatty acids.

But safety.

(HW) Clostridium - narrow parameter

(SM) Fatty acid composition

1 1
Reviews of monographs of concentrated fish oils
(SM) Attach fish^{oil} label - deliver^{no} EPA

Functions - 2 separate types of substances

Revised guidelines

Fish products very different from fish

(LB) Price

(RO) Krill oil

Fish oil (1 or 6 capsules/day)

2 sponsors -

(RO) Krill oil not concentrated

Taxa B. astaxanthi

(LB) AZDA

Antioxidant

(LB) 2009 - show where safe

(RO) 2-3

Astaxanthin 110-150 - less than 150

that is the active.

(LB) USP monograph

Will revise guideline

Doesn't know what will be on it.

(RO) 'No recam. no advice

Dilemma with various sponsors

Opportunity to review role of compositional guidelines

(RO) 3rd option

- 2 different comp guidelines

- differentiate on register

LB Are they different substances

(AB) Look different.

(SM) Accept

New substance -

Analog - separate substance, different

Difficult how assessed.

1985 1985 - Lancer Garlic isn't Garlic

Range of comp guidelines depending how produced.

Azod, aqueous

All different

Narrow called garlic - class

Fits into some categories.

Class of kill oil

Different substances

JB

How narrow produces literary variable.

JB Analogs - racem - difference is here chemical

Fingerprint profile

Narrow profile variation.

HW

Different solvents

Solvent does

Narrow variation

Processing

RO

"Solvent solvent"

Naming issue - AMN, Na + Part + Prep

Not specific on preparation.

AB

Issues

Not sure Options are

Option 1 or 2 - accept old or new

RO

Either, or, both.

JB

Old guideline stays.

Originator - do not contain our language

Will have to take regulatory action.

SM

Focus on fish oil, kill oil - fatty acid content.

Based on solvents - action pulls out fatty acids.

Look at profiles in detail - action different from alcohol.

2 different preparations

Based on extraction method > different profiles.

SM

2 - action

Other organic solvents. BP compliance.

2 ways deal with kill oil -

How many comp guidelines for fish oil

JB

Multiple.

JB

C

JB Nephene
LAKER

The EU say the same

AB Influential - not different between Nephene and
Ako Biomarine (leaves EPA OMA) influence our
decision.

JB Compared in EU - said the same.

AB Does animal efficacy
biomarker of constitutive
biological activity

SN Nephene - different biological activity.
Substantive differences between substances.

LD One weaker, one stronger

check

~~JB The EU is not a scientific body. It is a political body. It is not a scientific body. It is a political body.~~
~~Somebody is a scientist.~~

AB Concede EU - similar enough.
Demand - further action.
Quality definition of product.

HW What advantage

AB How in practice
Clearly damages different
lowering triglycerides
Difficult for consumers.

HW Fish oil different names - confusion.

RO 2 products both with kill oil
Sponsors hold evidence.
Decision to consumer

Consumer - still told how to use

AB What for industry if 2 guidelines
USP in a year's time.

When ingredients separated it to 2

JB enzymic - hexan and ethanol - BP solvents

When do we draw the line.

(AB) Fish oils overlap.

(LB) Multiple garlic - new standard - ? workable.

Review role of compositional guidelines

Hexan - reflect difference in quality with USP
comes in place.

RV composition & difference between ingredients.

(RO) All people comply with krill oil

Accept 1

Set up a standard for short period of time.

(LB) Procedure - Garlic plus.

Similar reason.

How different is different and does it matter?

(MS) Listed max - nothing wonderful
established product

Registration - innovation

Does it come in?

Jenny - fish oil CA

(SM) 2 compositional guidelines - out to industry
consultation

1 comp guideline

Procedural - function of TGA has to fit in
national medicine

Significant issues

Chemical perspective - 2 eg of collapsible/combined.

If comp g broad not taking into account
individual components.

Revise

AB

RO Second material not evaluated - not safe.

Suspect until shown to be safe.

JB Differ on quality, safety

When part of Act to cease supply

Differ substance not eligible for listing

SM either specification is safe. even though different.
No concern re safety issue - but as distinct.
Solvent extraction method result is different constituent profile.
Now, in 10 years - separate.

JB When with herbal substances
Standardised against different compounds.

SN No concern re safety
Could be same class of substance
Class - Kiri oil. 2~~3~~ compositional guidelines
Value listed - critical

- Kava significant deliberation

Kava - guidelines

- Particular extract - criteria for listing - by default comp guideline

AB ① Kiri oil Listable substance? whether comp guideline or not.
written in requirements.
now at present.

Is acceptable whether comp guideline

RO ① Not a restriction

② No major concerns re safety

Products on market eligible to stay there.

Approved Listable substance, no safety concern.

2 OK from safety

No formal evaluation presented to AECM.

Based on material input.

③ ① Different solvents, different constituent profile.
fish oils

separate guideline

different comp guideline

Neptune and Superba

AZPA would not want their guideline notified

ENZ motif - different.

What is the shape of comp guideline

Not for safety, only to provide constituent profile.

④ Acknowledges USP underway, any advice would
be eclipsed with USP monograph.

⑤ Review role of comp guideline
market advantage, exclusivity

Acknowledged permitted for use, irrespective of whether complier with guideline or not

(LB) ~~PP~~ solvers.

(PC) Expand comp guideline

Give sponsor chance to provide submission. -

(CB) Bringing to APCM

→ commercial aim

(MS) Role of compositional guidelines.

Shared info between ourselves and

- no new data

(AB) Rebuttal around safety would have come out.

(PC) Broader comp guideline, no safety concern.

First application chance of rebuttal

(AB) Accept revised?

(PC) Yes

(AB) 2 guidelines

(CB) Differentiated - solver -

(2) - not safety

- quality? not sure.

(CW) Hebs - differentiated on plan put, prep, solver.

(AB) 1 - narrow, make error

2 - - safe, recognise different problem and quality, reflect in design.

Other comp needs also differ significantly.

Perhaps not enough.

(PC) Advantage of having Kill 1 or 2

→ just confusion.

(AB) different quality, different messages.

as happens with everything else.

(SM) Can to time with issue

• guideline - revise current guideline.

• all meet

• overused in a year's time.

• Academic

(CB)

BW

AB Vote

① ACCM recognize Kill oil as approved listable substance inspection of whether it complies with the CG

② Based on preserved data, ACCM identified no safety concerns in either CG, providing ^{Kill oil is} identified and BP compliant solvents

③ ACCM recognize a difference in ^{processing} solvents used, resulting in different constituent profiles that result in ~~some~~ ^{variation} in quality parameters in final product.

Not uncommon in natural products. Therefore not a strong argument for more than 1 comp guideline to define safe kill oil. Noting variations in active constituent profile will be reflected in final dosage of therapeutic product. substance.

1 recognition of Do or go with Option 2

SM. BP solvent

AB Vote

Option 2

③
④

④ Note USP is developing

→ ^⑤ Re-examine role of compositional guidelines

RR

Whales starving as a result
algae

Kill Oil

No legal requirement

Why an issue?

Almost a non issue.

New Proprietary rights to an ingredient.

Does need to comply?

Yes it is Kill oil - safety data not CA

Who cares?

Camp g. becoming mandatory

Can enforce a camp guideline

Condition of listing - written into definition of ingredient

Can camp guidelines be part of ingredient rule.

Not mention list of contaminants.

Can add leaf

Requirement of listing, not camp guidelines

Requirement of ingredient.

Do have capacity to review efficacy.

Dosage

Look at dosage and efficacy of medicine.

Evidence to support use.

Questions about therapeutic use, premise pick up in

Post Market.

Cannot look at efficacy of new listable substance.

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Sign off on active ingredient.

Camp guideline not mandatory.

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No docs to describe.

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Likely to arise.

Any sponsor can put any Kill oil

have an own guideline.

Different sponsors can use different Kill oils

No issue

① Need legal underpinning $\rightarrow$ clarity

② Commercial - exclusivity of substance
- use etc

Is exclusivity something that should be considered

Train out of control

Are they delivering what we need?

Legislate or find alternative

Task - original commissioned guidance

Essentially same, different paradigms.

How are they created?

Concerning

Specification criteria

- Periodic 10 fold lessening of

Parasitic 1.6 to 2

transfer .1 to .2

not nearly nice or clean.

By broadening criteria, compromising safety.

1st produce higher quality

Ref. better, quality declined $\Rightarrow$ different substances.

Quoting haven't changed?

Matter of safety

less than allowed in fish oil

From a safety aspect not issue.

Markets were evaluated for safety

New substances - evaluated and added

Description.

Spencer B, same but different - is it sufficiently similar

Don't submit to TGA

Any know if they let us know.

Matter and shot up.

Significant differences e.g. fatty acids.

But safety.

Guideline - narrow parameter

Fatty acid composition

Review of development of concentrated fish oils

Attach fish oil - deliver ^{no} EPA

Function - 2 separate types of substances

Revised guidelines

End product very different from fish

Price

Kill oil

Fish oil (1 or 6 capsules/day)

2 sponsors -

Kill oil not concentrated

Tax B. astaxanthi

AZDA

Aquamarine

2009 - okay shore safe

Pa 2-3

Astaxanthi 110-150 - less than 150

that is the active

USP monograph

Will provide guidance

Doesn't know what will be on it

No recom, no advice

Dilemma with various sponsors

Opportunity to review role of compositional guidelines

3rd option

- 2 different comp guidelines

- differentiate on register

Are they different substances

look different

Accept

New substance -

Analog - separate subcategory different

Difficult how assessed

1985 1985 - Lancer Garlic is Garlic

Range of comp guidelines depending how produced

Ased, aqueous

All different

Narrowly called garlic - class
Fits into same category.
Class of kill oil
Different substances

Narrow produces identity variable.
Analog - racem - difference is here chemical
Fingerprint profile
Narrow profile variation.
Different solvers
Solver does
Narrow variation
Processing
"Suitable solver"

Naming issue - AMN. Name + Part + Prod
Not specific on preparation.

Issues

Not sure Options are

Option 1 or 2 - accept old or new

Either, or, both.

Old guideline stays.

Questioner - do not contain our guideline

Will have to take regulatory action.

Focus on fish oil, kill oil - fatty acid covered.

Based on solvers - action pulls out fatty acids

Look at profiles in history - get the different from old

2 different preparations

Based on extraction method $\rightarrow$ different profiles.

2 - action

Other organic solvers BP compliance.

2 ways deal with kill oil -

How many comp groups for fish oil

Multiple.

Neptune

The EU say the same

Influenced - not difference between Neptune and

(laws EPA OMA) influence our

decision.

Compound in EU - said the same.

Does annual efficacy

biomarker of constituents

biological activity

Neptune - different biological activity.

Substance differences between substances.

One weaker, one stronger

Conclude EU - similar enough.

Debate - further again.

Quality definition of product.

What advantage.

How in practice

Clearly dosages differ

lowering triglycerides

Difficult for consumers.

Fish oil different names - confusion.

2 products both with kill oil

Spencer holds evidence.

Difficult to consumer

Consumer - still told how to use

What for industry if 2 guidelines

USP in a year's time.

When ignored separated it to 2

enzymatic - hexam and shanol - BP solves

When do we draw the line.

Fish oils overlap

Multiple garlic - new standard - ? workable.

Previous role of compositional guidelines

harmon - reflect difference in quality with US
exists in place.

RV compositional & difference between ingredients.

All people comply with krill oil

Accept 1

Set up a standard for short period of time.

Procedure - Cuckoo plus.

Similar reason.

How different is different and does it matter?

Listed material - nothing wonderful

established product

Registration - innovation

Does it come in?

- fish oil CC

2 compositional guidelines - out to industry
consultation

1 comp guideline

Procedural - function of TGA has to fit in
national medicine

Significant issues

Chemical perspective - 2 eg of collapsible/combined.

If comp g broad not taking into account
individual components.

Revise

Second material not evaluated - not safe.

Suspend until shown to be safe.

Differ on quality, safety

When part of Act to cease supply

Differ substance not eligible for listing

either specification is safe. even though different,

No concern re safety issue - but as distinct.

Solvent extraction method result is different constituent profile.

Now, in 10 years - separate.

When with herbal substances

Standardised against different compounds.

No concern re safety

Could be same class of substance

Class - Kiri oil. 2nd compositional guidelines

Value listed - critical

Kava - significant devaluation

Kava - guidelines

- Particular extract - criteria for listing - by default comp guideline

① Kiri oil Listable substance? whether comp guideline or not.

within a requirement.

non-at present.

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② No major concerns re safety

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market advantage, exclusivity

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PP solvers.

Expand camp guideline

Give sponsor chance to provide submission.

Referring to APCM

→ commercial aim

Role of competition guidelines.

Shared info between sponsors and

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Rebuttal around safety would have come out.

Broader camp guideline, no safety concern.

First application chance of rebuttal

Accept revised?

Yes

2 guidelines

Differentiated - solver-

- not safety

- quality? not sure.

Herbs - differentiated on plan part, prep, solver

1 - narrow, make clear.

2 - safe, recognise different profiles and quality reflects in design.

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Vote

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Not uncommon in natural products. Therefore not a strong
argument for more than 1 comp guideline to define
safe kill oil. Noting variations in active
constituent profile will be reflected in final
dosage of therapeutic product. Substance.

1. ~~recognition of~~ Do us go with Option 2
BP solvents

Vote

Option 2

③ ④ Note USP is developing

⇒ Re-examine role of compositional guidelines

Whales starving as a result
algae