EXHIBIT E

ARKANSAS DEPARTMENT OF HEALTH

(3513)

<u>SUBJECT</u>: List of Controlled Substances

DESCRIPTION: The proposed listed amendments update the List of Controlled Substances to include these drugs. Items one through nine are additions made to the controlled substance list per Emergency Rule. The following items listed will include Emergency Rule additions and listed substances by current rule making procedure.

1. 25B-NBOH. 2-[[[2-(4-bromo-2,5-dimethoxyphenyl)ethyl]amino]methyl]-phenol. Page 5, (47). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this hallucinogenic substance with no recognized medical use be included into Schedule I. Page 5, (47).

2. 25I-NBOH. 2-[[[2-(4-iodo-2,5-dimethoxyphenyl)ethyl]amino]methyl]-phenol, Page 5, (48). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this hallucinogenic substance with no recognized medical use be included into Schedule I. Page 5, (48).

3. 5-Fluoro-ADB. methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)- 3,3dimethylbutanoate. Page 21, (K)(xviii). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid with no recognized medical use be included into Schedule VI. Page 21, (K), (xviii).

4. 5-Fluoro-MDMB-PICA. methyl 2-(1-(5-fluoropentyl)- 1H-indole-3carboxamido)-3,3-dimethylbutanoate. Page 21, (K), (xix). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid with no recognized medical use be included into Schedule VI. Page 21, (K), (xix).

5. MDMB-CHMICA. methyl 2-(1-(cyclohexylmethyl)-1H-indole-3- carboxamido)-3,3-dimethylbutanoate. Page 21, (K)(xx). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid with no recognized medical use be included into Schedule VI. Page 21, (K), (xx).

6. FUB-AMB. methyl 2-(1-(4-fluorobenzyl)- lH-indazole-3-carboxamido)-3methylbutanoate. Page 21, (K), (xxi). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid with no recognized medical use be included into Schedule VI. Page 21, (K), (xxi).

7. MDMB-FUBINACA. methyl 2-(1-(4-fluorobenzyl)- lH-indazole-3carboxamido)-3,3-dimethylbutanoate. Page 21, (K)(xxii). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this synthetic cannabinoid with no recognized medical use be included into Schedule VI. Page 21, (K), (xxii).

8. The addition of a section in Schedule V titled Other Substances page 17, (f).

To incorporate the addition of a new Schedule V substance by DEA.

9. A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3- methyl-6R-(l- methylethenyl)-2-cyclohexen- l-yl]-5-pentyl-1,3- benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols. Page 17, (f), (1). To follow DEA scheduling, this drug would be included as Schedule V. Page 17, (f), (l).

10. AB-PINACA. N-(1-amino-3-methyl-l-oxobutan-2-yl)-1-pentyl-lH-indazole-3caroboxamide. Page 21, (K)(xxiii). The DEA has scheduled this synthetic cannabinoid because it has no recognized medical use. This drug would be included as Schedule VI. Page 21, (K), (xxiii).

11. AB-CHMINACA. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide. Page 21, (K), (xxiv). The DEA has scheduled this synthetic cannabinoid because it has no recognized medical use. This drug would be included as Schedule VI. Page 21, (K), (xxiv).

12. THJ-2201. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl) methanone. Page 18, (B), (xvi). The DEA has scheduled this synthetic cannabinoid because it has no recognized medical use. This drug would be included as Schedule VI. Page 18, (B), (xvi).

13. Dronabinol in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration; [(-)-delta-9-trans-tetrahydrocannabinol (delta-9-THC)], Page 9, (f), (2). To follow DEA scheduling, this drug would be included as Schedule II. Page 9, (f), (2).

14. 25E-NB0Me. 2-(4-ethyl-2,5-dimethoxyphenyl)-N-[(2methoxyphenyl)methyl]ethanamine. Page 5, (49). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this hallucinogenic substance with no recognized medical use be included into Schedule I. Page 5, (49).

15. 25H-NBOMe. 2-(2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl) methyl]ethanamine, Page 5, (50). Felisia Lackey, Chief Forensic Chemist- Drug Section, Arkansas State Crime Laboratory, requested that this hallucinogenic substance with no recognized medical use be included into Schedule I. Page 5, (50).

16. 25C-NBOH. 2-(((2-(4-chloro-2,5-dimethoxyphenyl)ethyl]amino]methyl]-phenol. Page 5, (51). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this hallucinogenic substance with no recognized medical use be included into Schedule I. Page 5, (51).

25H-NBOH. 2-[[[2-(2,5-dimethoxyphenyl)ethyl]ami no]methyl]-phenol, Page 5,
 (52). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime

Laboratory, requested that this hallucinogenic substance with no recognized medical use be included into Schedule I. Page 5, (52).

18. N-Ethylpentylone. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-pentan-1-one. Page 7, (11), (b), (18). Felisia Lackey, Chief Forensic Chemist-Drug Section, Arkansas State Crime Laboratory, requested that this stimulant substance with no recognized medical use be included into Schedule I. Page 7, (11), (b), (18).

- 19. Two items with typos marked for clean-up.
 - Page 20, I, (ix).
 - Page 21, (K) (xvi).

<u>PUBLIC COMMENT</u>: A portion of this rule was reviewed and approved by the Executive Subcommittee at its meeting on April 8, 2019, for emergency promulgation. With respect to permanent promulgation, a public hearing was held on January 16, 2019. The public comment period expired on January 16, 2019. The Department received no public comments. The proposed effective date is upon legislative review and approval.

FINANCIAL IMPACT: This rule has no financial impact.

LEGAL AUTHORIZATION: The Director of the Department of Health shall administer the Uniform Controlled Substances Act, Arkansas Code Annotated § 5-64-101 et seq., and may add a substance to or delete or reschedule any substance enumerated in a schedule under the procedures of the Arkansas Administrative Procedure Act, § 25-15-201 et seq. *See* Ark. Code Ann. § 5-64-201(a)(1)(A)(i). In making a determination regarding a substance, the director shall consider the following: (1) the actual or relative potential for abuse; (2) the scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the substance; (4) the history and current pattern of abuse; (5) the scope, duration and significance of abuse; (6) the risk to public health; (7) the potential of the substance to produce psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled under the Uniform Controlled Substances Act. *See* Ark. Code Ann. § 5-64-201(a)(2).

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY	Arkansas Department of Health Pharmacy Services and Drug Control			
DIVISION				
DIVISION DIRECTOR	Shane David, Pharm.D. Shane David, Pharm.D. Slot 25, 4815 West Markham, Little Rock, AR 72205			
CONTACT PERSON				
ADDRESS				
PHONE NO. 501 661-23 NAME OF PRESENTER A' MEETING	T COMMITTEE			
PRESENTER E-MAIL La	Laura Shue, General Counsel			
	INSTRUCTIONS			
 C. If you have a method of in this Rule" below. D. Submit two (2) copies of the third of the two (2) copies of two (2) copies of the two (2) copies of the two (2) copies of two (2) copies of the two (2) copies of two (2) copies of the two (2) copies of two (2) copies	s form for future use. ion <u>completely</u> using layman terms. You may use additional sheets, if ndexing your rules, please give the proposed citation after "Short Title of this questionnaire and financial impact statement attached to the front of osed rule and required documents. Mail or deliver to:			
····· (-) -opies of the prop	oscur une and required documents. Mail or deliver to:			

Donna K. Davis Administrative Rules Review Section Arkansas Legislative Council Bureau of Legislative Research One Capitol Mall, 5th Floor Little Rock, AR 72201

1. What is the short title of this rule?

**

List of Controlled Substances

2. What is the subject of the proposed rule?

The scheduling of controlled substances.

Yes 🗌

3. Is this rule required to comply with a federal statute, rule, or regulation?

If yes, please provide the federal rule, regulation, and/or statute citation.

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act?

If yes, what is the effective date of the emergency rule?	Yes \square No \boxtimes (Portion of list is in effect via emergency rule $11/01/18$ —05/01/19)

When does the emergency rule expire?

Revised January 2017

No 🛛

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No 🖂 5. Is this a new rule? Yes No 🖂 If yes, please provide a brief summary explaining the regulation. Does this repeal an existing rule? Yes No 🛛 If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. Is this an amendment to an existing Yes 🖂 No rule? If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. Note: The summary should explain what the amendment does, and the markup copy should be clearly labeled "mark-up." 6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Ark. Code Ann. §§ 5-64-201 - 5-64-216 7. What is the purpose of this proposed rule? Why is it necessary? Update to the List of Controlled Substances for the State of Arkansas. 8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). http://www.healthyarkansas.com/rules regs/rules regs.htm 9. Will a public hearing be held on this proposed rule? Yes X No If yes, please complete the following: Date: 01/16/19 Time: 10:00 a.m. Room #2512 of the Dept. of Health Bldg. at 4815 West Markham, Little Place: Rock, AR 10. When does the public comment period expire for permanent promulgation? (Must provide a date.) January 16, 2019, 4:30 p.m. 11. What is the proposed effective date of this proposed rule? (Must provide a date.) May 1, 2019 12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice.

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library as required pursuant to Ark. Code Ann. § 25-15-204(e).

Revised January 2017

Special Revenue Other (Identify)	0 0	Special Revenue Other (Identify)	0
Total	0	Total	0

(b) What is the additional cost of the state rule?

Current Fiscal Y	ear	Next Fiscal Year	
General Revenue	0	General Revenue	0
Federal Funds	0	Federal Funds	0
Cash Funds	0	Cash Funds	0
Special Revenue	0	Special Revenue	0
Other (Identify)	0	Other (Identify)	0
Total	0	Total	0

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year		Next Fiscal Year
\$	0	\$_0

This is an uncontrolled and unregulated substance. It would be purely speculative as to the revenue loss that might occur for those selling the product.

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year	Next Fiscal Year
\$_0	\$_0

This is an uncontrolled and unregulated substance. It would be purely speculative as to the revenue loss that might occur for those selling the product.

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

Yes 🗌

No

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

Revised January 2017



Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000 Governor Asa Hutchison Nathaniel Smith, MD, MPH, Director and State Health Officer

SUMMARY OF PROPOSED AMENDMENTS TO RULES AND REGULATIONS PERTAINING TO THE LIST OF CONTROLLED SUBSTANCES FOR THE STATE OF ARKANSAS

The proposed listed amendments update List of Controlled Substances to include these drugs. Items one through nine are additions made to the controlled substance list per Emergency Rule. The following items listed will include Emergency Rule additions and listed substances by current rule making procedure.

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